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Attorneys at Law

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May 25, 2017

Magistrate Judge Sherry R. Fallon
United States District Court
844 N. King Street
Wilmington, DE 19801-3555

Re: *AbbVie Inc. v. Amgen Inc.*, C.A. No. 16-666-SLR-SRF

Dear Judge Fallon:

During the May 9 discovery conference, the Court considered Amgen's motion to compel AbbVie to produce select documents generated during the "patent exchange" between AbbVie and other companies that, like Amgen, are seeking to market a biosimilar of Humira and believe AbbVie's patents to be invalid. Amgen submits this letter-brief in response to the Court's request for additional briefing on this issue.

The Biologics Price Competition and Innovation Act ("BPCIA") sets forth a series of pre-litigation steps—starting shortly after the FDA begins review of the biosimilar application—for parties to identify which patents may be infringed and exchange contentions concerting the validity, enforceability, and infringement of those patents. This "patent exchange" starts with the biosimilar applicant (here, Amgen) providing a copy of its application ("BLA") and manufacturing information to the owner of the product that is already on the market (called the "reference product sponsor," here AbbVie). The sponsor then must give the biosimilar applicant "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor," also known as a "3(A) list." 42 U.S.C. § 262(*l*)(3)(A)(i). For each patent on the 3(A) list, the biosimilar applicant must give the reference product sponsor a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [biosimilar] applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product." *Id.* § 262(*l*)(3)(B)(ii)(I). After receiving the applicant's response, the sponsor must provide its own statement, on a claim-by-claim basis, with respect to the validity, enforceability, and infringement of each patent. *Id.* § 262(*l*)(3)(C). The applicant's statement is sometimes referred to as a "3(B) statement," the sponsor's statement as a "3(C) statement," and both of these statements as "patent exchange contentions."

Just as Amgen and AbbVie engaged in the "patent exchange" before this litigation was filed, AbbVie has participated (and will further participate) in similar exchanges with third parties that, like Amgen, are seeking to market a biosimilar to Humira and believe AbbVie's patents to be invalid. As part of its Request for Production No. 25, Amgen requested the patent exchange contentions that AbbVie has exchanged or will exchange with other Humira biosimilar applicants. (D.I. 60 at III.A.2.)

After the May 9 conference, Amgen offered to limit its request for patent exchange contentions to *only* the portions that concern the invalidity and validity of (i) the patents-in-suit and (ii) any patents that share a common priority with the patents-in-suit. Amgen explained that it does *not* want the infringement contentions or any confidential information of the other applicants—that information should be redacted before produced to Amgen. In

response to Amgen's offer, AbbVie agreed to produce the requested documents but *only if* Amgen also agreed to withdraw its request for documents from foreign proceedings in the UK that the Court had already *ordered* AbbVie to produce. (Ex. A, May 9 Hr'g Tr. at 162:9–163:9; Ex. B.) When Amgen refused to accept AbbVie's purported "compromise," AbbVie refused to produce the requested BPCIA documents, forcing Amgen to continue to seek the Court's help.

AbbVie does not dispute the relevance of the requested documents. The reasons why the asserted patents and the Related Patents are invalid, according to other biosimilar applicants and AbbVie's expressed opinions in response, are relevant to Amgen's invalidity defenses. For example, the other biosimilar applicants may have found prior art references that are currently not known to Amgen, or identified other defects in AbbVie's patents that Amgen has not yet discovered. Seeing any additional prior art or invalidity defenses would give Amgen notice that AbbVie will be providing responses to these positions in the patent exchange, and if the patents are asserted in a subsequent litigation, in that subsequent litigation. Amgen is entitled to learn whether AbbVie has taken any inconsistent or shifting positions when responding to the validity defenses of other biosimilar applicants.

Documents relating to the invalidity of asserted and related patents from other proceedings are routinely produced in discovery, especially when they have a direct bearing on the claims and defenses of the parties. For example, in *Wyeth v. Impax Laboratories, Inc.*, the plaintiff agreed to produce "all relevant documents from the Teva Litigation, namely, *those dealing with claim construction and patent validity*," in part because the patents at issue in the Teva Litigation were the same patents at issue in that case. 248 F.R.D. 169, 170 (D. Del. 2006) (emphasis added). In *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 662 F. Supp. 2d 375, 380–84 (D. Del. 2009), this Court ordered production of documents from other proceedings involving related patents where the defendant had made a specific showing that they had a "direct bearing on the claims and defenses asserted in the instant litigation." Here, Amgen has made the requisite showing—Amgen has not requested *all* documents from the patent exchanges or even all of the 3(B) and 3(C) statements. Instead, Amgen has appropriately focused its document request in accordance with this Court's holdings—the invalidity and validity sections of the 3(B) and 3(C) statements for the patents-in-suit and those that share a common priority with the patents-in-suit.

There is no burden (let alone undue burden) associated with producing the requested documents. The requested portions of the 3(B) and 3(C) statements can be clearly identified and easily produced to Amgen. Nor are these documents difficult for AbbVie to collect, since they were (or will be) sent directly to AbbVie's outside counsel as part of the BPCIA pre-litigation process.

AbbVie previously argued that "Amgen improperly seeks highly confidential information about which of its competitors have or have not filed aBLAs for adalimumab, which would give Amgen a heads up on its competitors' launch timing." (D.I. 65 at 6.) But as AbbVie has recognized, the timing of the BLA filing does not disclose when the biosimilar applicant will launch its product—that is one reason why the biosimilar applicant must serve a "notice of commercial marketing" under the BPCIA. (*See* 42 U.S.C. § 262(*l*)(8)(A); D.I. 20.) Amgen's focused document request does not seek other biosimilar applicants' notices of commercial marketing. And, contrary to AbbVie's argument, many biosimilar applicants have not treated the

mere fact that they have filed a BLA with the FDA as confidential information, as shown by the issuance of the following press releases. (*See, e.g.*, Ex. C (Boehringer Ingelheim's Humira Biosimilar); Ex. D (Amgen's Humira Biosimilar); Ex. E (Sandoz's Neupogen Biosimilar); Ex. F (Apotex's Neupogen Biosimilar); Ex. G (Apotex's Neulasta Biosimilar); Ex. H (Sandoz's Neulasta Biosimilar); Ex. I (Coherus's Neulasta Biosimilar); Ex. J (Amgen and Allergan's Avastin Biosimilar).)

Indeed, AbbVie has also argued that invalidity contentions exchanged during the patent exchange are not confidential. When AbbVie and Amgen participated in the patent exchange last year, AbbVie requested copies of Amgen's 3(B) statements with the non-infringement sections redacted. AbbVie argued that "your [*i.e.*, Amgen's] validity positions clearly aren't confidential under the statute unless they contain confidential information about your product (which we don't think they do)." (Ex. K.)

Even if the fact that a biosimilar competitor has filed an adalimumab BLA application is considered to be confidential, AbbVie's professed concern that Amgen will use this information to its "competitive" advantage is obviated by the protective order in this case. The protective order (i) limits Amgen's use of confidential information to this litigation, (ii) limits disclosure of such information to only four in-house attorneys, who cannot disclose it to others at Amgen, and (iii) bars recipients from participating in any competitive decision-making at Amgen. (D.I. 37 at 1; D.I. 55 at ¶¶ 27, 31, 36.) The protective order also provides a mechanism for the disclosure and protection of third-party confidential information. (D.I. 55 at ¶ 3.) Other courts have recognized that protective orders like the one in this case provide sufficient protection for the confidential information of third parties, including where a plaintiff is compelled to produce third-party submissions from related litigation. *See Apple Inc. v. Samsung Elecs. Co.*, No. C11-1846, 2012 WL 1232267, at *6 (N.D. Cal. Apr. 12, 2012) ("[T]he court sees no reason that the protective order in this case is inadequate to protect third-party confidentiality interests.").

At the May 9 hearing, AbbVie also made the new argument that Amgen was not entitled to the requested discovery because AbbVie's BPCIA exchanges with third-party Humira biosimilar applicants are "akin to settlement communications." (Ex. A, May 9 Hr'g Tr. at 154:8–21.) AbbVie attempts to blur the line between the patent exchange documents that Amgen has requested and those it has not. Under the BPCIA, after the reference product sponsor (*i.e.*, AbbVie) and the biosimilar applicant exchange their invalidity and infringement contentions, the participants negotiate the scope of the subsequent litigation—*i.e.*, which patents will be litigated in an immediate patent infringement action and which patents, if any, will be reserved for a later phase of the case. *See* 42 U.S.C. § 262(*l*)(4)–(5). Amgen has not requested these patent negotiation documents. And even if the documents that Amgen *has* requested *were* "settlement communications," that does not mean that they would be exempt from discovery. *See* Fed. R. Civ. P. 26(b)(1) ("Information within this scope of discovery need not be admissible in evidence to be discoverable.").

Finally, AbbVie also argues that Amgen will ultimately receive the documents requested by Amgen once each of the BPCIA proceedings ripens into litigation. Not so. The contentions exchanged by the parties to a BPCIA patent exchange do not necessarily become public once a patent litigation is initiated. And the contentions exchanged later in litigation are

not a substitute for the contentions exchanged earlier in the pre-litigation BPCIA patent exchange. Indeed, differences between those two sets of contentions might be highly relevant, particularly in light of litigation contentions having the benefit of discovery and being subject to local patent rules and any discovery limitations

Accordingly, Amgen requests that this Court order production of the requested patent exchange contentions within 14 days of (i) AbbVie's receipt of such contentions, in the case of 3(B) statements, or (ii) AbbVie's submission of such contentions, in the case of 3(C) statements.

Respectfully,

/s/ James L. Higgins

James L. Higgins (No. 5021)

JLH
cc: Counsel of Record (via CM/ECF)

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ABBVIE, INC. et al.,	:	
	:	
Plaintiffs,	:	No. 1:16-0666-SLR-SRF
	:	
v.	:	
	:	
AMGEN, INC. et al.,	:	
	:	
Defendants.	:	

Tuesday, May 9, 2017
10:00 a.m.

Discovery Dispute Hearing
Courtroom of Judge Sherry R. Fallon

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE Sherry R. Fallon,
United States District Court Magistrate

APPEARANCES:

McCARTER & ENGLISH
BY: MICHAEL KELLY, ESQ.
BY: DANIEL SILVER, ESQ.
-and-

LATHAM & WATKINS LLP
BY: MICHAEL MORIN, ESQ.
BY: CASEY DWYER, ESQ.
BY: DAVID FRAZIER, ESQ.
-and-

WILMERHALE
BY: JOSH STERN, ESQ.

On behalf Plaintiffs

APPEARANCES CONTINUED:

YOUNG CONAWAY STARGATT & TAYLOR LLP
BY: MELANIE SHARP, ESQ.
BY: JIM HIGGINS, ESQ.

-and-

CRAVATH, SWAINE & MOORE LLP
BY: KEITH HUMMEL, ESQ.
BY: ANDREI HARASYMIAK, ESQ.
BY: SHARONMOYEE GOSWAMI, ESQ.

On behalf of Defendants

note of why they think the patents are invalid or not infringed and it's actually places within this exchange where it's supposed to be a discussion about, can we license any of the patents, do we need to bring all of these patents-in-suit, there's negotiations and so forth.

The upshot is that frankly these are more akin to settlement negotiations than they are to pleadings that you have in the context of a litigation. I'm not going to go so far as to say that they would be covered by Rule 408. But in terms of the type of discovery and the relevance -- I heard Mr. Hummel say that these are highly relevant, I think the same types of considerations to go into saying that such negotiations are terribly relevant or should be protected in the context of what's applied here, these are papers that are prepared by counsel. They're not submitted to any court as pleadings, per se.

Ultimately, if there is litigation between the parties, those will be in court. Those would be public proceedings and Amgen and

everybody else would get the benefit of any positions that AbbVie takes with respect to those materials at the time that a court case actually happens.

Another key consideration here is they're asking for all of these. Again, I said there were 70 patents that were involved and there have been additional follow-ons since then. We only have 10 patents in this case.

It's not clear to me why they would get discovery. They're asking for the full BPCIA exchanges. At their request, we only brought suit on 10 patents, but now they are asking for full discovery of what other parties do in these BPCIA exchanges.

I want to go back to the confidentiality issue. Of course, there is a protective order. And we assume that Amgen and its counsel would abide strictly by that protective order. The fact of the matter is that this material is heavily intertwined.

Each of these productions by each of these Patent Dances is initiated by the production of a large amount of extremely

confidential material by their competitors. They have this as an extremely sensitive issue. It's the manufacturing information by multiple companies making biosimilar products.

And while there was an agreement here between Amgen and AbbVie that we would create redacted copies that could be shared with other people and so forth, I don't get the sense that I can make a redacted version and then call up and say to my opponent, some other biosimilar in interested, can I send this to Amgen because they're really curious about it.

It's not going to be a simple point, and that third party is not in front of this court. There's nothing that requires them to reach an agreement with us on what can or cannot be redacted. So we create all of these issues with third party confidential information that's in these BPCIA materials or really is it just a matter of them to get legal proceedings of briefs that are written by the lawyers on positions that will be apparent to them at the time that the litigation is actually matured.

So I would say that this is

something that will add a lot of complexity, create a lot of burden and have very little relevance. Briefly on the foreign proceedings, Your Honor, there was a massive effort to reduce the quantity of materials in that case. I think we're down to the question on the one that ends in 0053. That is not a related patent. This one is referred to as the Bannerjee. Actually, that's 17491, the Bannerjee patent that relates to psoriasis and rhuematoid --

THE COURT: Understood you've already made a partial reduction?

MR. FRAZIER: We've made a partial production, Your Honor, with respect to the ones that are related, the Hoffman patents. This Bannerjee patent is not related and it doesn't have anything to do with the dosing regimen being litigated in this case. I'm sure they're curious, but there's no particular reason to again go through the burden and complexity of sorting out these documents in these foreign proceedings for the sake of a patent that is really not related to the ones here in suit.

THE COURT: Okay.

MR. HUMMEL: Just on that last point, Ms. Goswami tells me that their Bannerjee and Hoffman, they are the same set of inventions and they are clearly related patents. These two sets of documents from the FujiFilm litigation, they are drawings, arbitrations, for some reason, I don't know. Again, I'm back to the more this is mysterious and the more they resist, the more I want it.

On the Patent Dance, there's a lot of argument there. I want to make it absolutely clear that we are not asking for the BLA. That's been submitted by the biosimilar applicants. I don't want that and I'm not asking for that. I'm asking for the 3(a) and 3(b).

The argument made by Mr. Frazier is the first time ever as far as I know said they are akin to settlement negotiations. There's nothing in the form of settlement negotiations in these exchanges back and forth. These are statutory exchanges. 408 by the way is a rule of evidence. It doesn't prevent discovery. It just prevents the use of it in

court.

And frankly, both sides in this case have referred, especially incorporated by reference parts of the 3(a) and 3(b) statements in their pleadings and certainly in the answer so I don't think that argument works at all.

In terms of this argument that eventually these will all become available, that's not true also. These are not going to become public statements once the litigation starts. Once the litigation starts, the parties will file whatever they are going to file in the court proceedings, but all of a sudden the BPCIA exchanges do not become public and anybody can walk up and find it. This is not the way this works. They're not filed with the FDA. They're not filed with the court. They're not filed anywhere.

They're asking, well, why do we want all of this. Again, these are the same patents you're asserting against other biosimilars and they're taking positions which may or may not be consistent here. In terms of confidentiality, I didn't hear Mr. Frazier deny

that they have redacted versions from these other proceedings. I bet my bottom dollar there are. I have emails from Mr. Morin saying certainly validity contentions 3(b) are not confidential and we're free to show them to anyone else and there's no confidentiality to the validity sections.

The bottom line here is these documents are directly related to the issues in the case. They are not going to be magically public in the future. This is the time that they be produced and we ask the Court to do so.

MR. FRAZIER: Your Honor, just a few points. First of all, I can categorically deny that we have a redacted version of files of an exchange from another party. But more importantly, this issue again with the third-party confidentiality is not a small one. I agree there must be legal statements here that are not necessarily confidential, but it's all intertwined that requires working with a party that is not before this court in order to decide what is appropriately redacted and given the volume of thousands of pages, it seems hardly

worthwhile.

And the point about it being -- I agree those particular documents are not going to become public. But to the extent that there are inconsistent positions, those positions will become public at the point when there's a litigation involved. So at that point they will be fully aware if AbbVie is forced to take inconsistent positions.

I will also note that we have a trial that is not until 2019, with the result of these other litigations will happen by that point. To the extent that there are Patent Dances and other competitors come in and do these exchanges and ultimately that litigation commences, those litigation positions will be apparent to Amgen.

MR. MORIN: Your Honor, I heard my name thrown in again. Mr. Hummel commented about some exchange that we had about confidentiality. I seem to recall Mr. Hummel responding and saying his request was not to be shared outside of the company which would be third parties. My recollection, I haven't

looked at these emails in a while, but that was my recollection of your request back that it was between two parties. Am I misremembering?

MR. HUMMEL: We had an understanding that we weren't going to publish them in the New York Times, and that's not the purpose. That's not our intent.

MR. MORIN: Your --

THE COURT: I'm ready to rule on this anyway. Let me first address the FujiFilm cases, the foreign proceeding. I'm going to grant the Motion to Compel and that takes care of Request for Production Nos. 9 and 10 of Amgen's set to the Plaintiff AbbVie.

It's difficult for me hearing what's been produced, what's been held back and without seeing the documents myself and having more detail, to say it's okay to make a partial production. If you're producing, you're producing it. Just produce the FujiFilm cases, the counterparts to the patents that Amgen is asking for.

They're saying these are family members of Hoffman patents or counterparts to

the Hoffman patents and, therefore, they ought to be produced. And if you've made the decision that some of the information at least is relevant and proportional to the needs of the case and you've produced it, make the production complete and I don't know how many times Plaintiffs would need to do that. Anything reasonable is satisfactory to the court. Can you give me an estimate?

MS. DWYER: We will need third-party's permission, Your Honor, so we will attempt it by the substantial completion date, but we need to see what the third party says.

THE COURT: With respect to the other documents, the Patent Dance documents, and I think that was the subject of the request for approximately 25, the BPCIA documents, again this is an issue I don't tread lightly in making a decision when I'm presented with arguments that this involves significant confidentiality issues involving third party biosimilar manufacturers who are not before the Court among other issues. That's not to cast aside the issues of relevance, of proportionality as well.

EXHIBIT B

From: <Michael.Morin@lw.com>
To: <KHummel@cravath.com>
Date: 05/19/2017 06:16 PM
Subject: RE: Schedule

Keith,

We maintain our positions on both the Enbrel documents we've requested and our objections with regard to the patent exchange documents with third parties. We believe we are entitled to the requested discovery on the Enbrel documents, and do not believe that production is warranted on the patent exchange documents. Nonetheless, in the spirit of compromise, and to avoid burdening the court, we've outlined counter-proposals on each of these issues here.

First, on the Enbrel documents, we're willing to accept your proposal with two modifications. First, Amgen would also collect documents from two Enbrel custodians, one most likely to have relevant information on Crohn's disease, and the other most likely to have such information on psoriasis, which would bring Amgen's total custodians to 25, as discussed at the hearing. Second, while we accept your representation that the documents you produce will "contain reasons for testing the selected dosing regimen; information about safety concerns (if any) relating to dosing regimens; and reasons why psoriasis and Crohn's disease were pursued as indications for Enbrel," we would reserve the right to re-raise this issue if, following your production, Amgen's production does not have sufficient information on these subjects.

Second, on the subject of patent exchange documents with third parties, we would be willing to agree to your request that we provide invalidity (but not noninfringement) contentions of any third parties for the patents in suit and other patents that share common priority (i.e., are related), provided that (1) we will need to give notice and an opportunity to object/intervene to any such third parties; and (2) you agree that for consistency, we can limit our production from foreign proceedings to patents that meet the same criteria for relatedness.

Thanks, and have a good weekend.

Mike

From: Keith Hummel <KHummel@cravath.com<mailto:KHummel@cravath.com>>
Date: Thursday, May 18, 2017, 12:52 PM
To: Morin, Mike (DC) <Michael.Morin@lw.com<mailto:Michael.Morin@lw.com>>
Subject: RE: Schedule

Here it is.

Amgen is willing to conduct a search of reasonable scope for (i) the IND applications for the study of Enbrel in the treatment of patients with psoriasis (the "Psoriasis IND") and Crohn's disease ("the Crohn's IND"), (ii) the clinical trial study reports for the studies conducted under the Psoriasis

IND and the Crohn's IND, and (iii) the clinical study protocols for the studies conducted under the Psoriasis IND and the Crohn's IND. We believe these documents contain reasons for testing the selected dosing regimen; information about safety concerns (if any) relating to dosing regimens; and reasons why psoriasis and Crohn's disease were pursued as indications for Enbrel.

Amgen is also willing to undertake a search of reasonable scope for documents and correspondence relating to clinical studies in patients with Crohn's disease conducted by third-party investigators and supported by Immunex.

Amgen is also willing to conduct a search of reasonable scope for documents relating to the Enbrel prior art scientific publications cited in Amgen's 3(B) statement for U.S. Patent No. 8,986,963 that were supported by Immunex or included an author affiliated with Immunex.

From: <Michael.Morin@lw.com>
To: <KHummel@cravath.com>
Date: 05/18/2017 10:53 AM
Subject: RE: Schedule

I'll check. When do you plan to send the Enbrel proposal?

From: Keith Hummel <KHummel@cravath.com<mailto:KHummel@cravath.com>>
Date: Thursday, May 18, 2017, 10:41 AM
To: Morin, Mike (DC) <Michael.Morin@lw.com<mailto:Michael.Morin@lw.com>>
Subject: Schedule

Mike,

We can move the schedule a few days. What specifically would you like to do?

Keith

Latham & Watkins LLP

Latham & Watkins LLP

EXHIBIT C

PR Newswire
a CISION company

Boehringer Ingelheim biosimilar candidate to Humira® accepted for EMA and FDA regulatory review

-- BI 695501 EMA and FDA applications are first biosimilar regulatory filings for Boehringer Ingelheim

-- Applications are supported by a comprehensive data package comprised of analytical, pre-clinical & clinical development studies

NEWS PROVIDED BY
Boehringer Ingelheim →
18 Jan, 2017, 09:00 ET

RIDGEFIELD, Conn., Jan. 18, 2017 /PRNewswire/ Boehringer Ingelheim announced today that BI 695501, its adalimumab biosimilar candidate to Humira®*, has been accepted for regulatory review by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

"The acceptance of our regulatory filings by the FDA and EMA is a critical milestone as we explore innovative ways for biosimilars to expand overall treatment options and seek to improve the lives of patients with chronic and life threatening diseases," said Martina

Flammer, Vice President, Clinical Development and Medical Affairs, Specialty Care, Boehringer Ingelheim Pharmaceuticals, Inc. "If approved, we believe BI 695501 can offer a high quality, economically sustainable treatment option to patients with inflammatory diseases in the U.S."

Boehringer Ingelheim is seeking approval for BI 695501 as a biosimilar to Humira® in the European Union and the United States. Adalimumab is a monoclonal antibody that blocks TNF α, an important mediator of inflammation in the human body. Adalimumab is approved as a biologic medicine under the brand name Humira® in many countries for the treatment of multiple chronic inflammatory diseases, such as rheumatoid arthritis, inflammatory bowel disease, and psoriasis. These disorders collectively affect the lives of 5 10% of the world population including 23.5 million people in the U.S. and approximately 36.3 million people in Europe.

Top line results from the completed Phase III study for BI 695501 in patients with active rheumatoid arthritis were announced on October 26, 2016.

About Boehringer Ingelheim in Biologics and Biosimilars

Boehringer Ingelheim is one of the largest producers of biologic medicines in the world. As a pioneer in biologics with more than 35 years of experience, the company has manufactured more than 25 biologic medicines for global markets. This includes monoclonal antibodies in oncology and immunology, interferons, and other targeted medicines that are routinely used to treat many patients across a broad range of therapeutic areas. Boehringer Ingelheim further builds on its commitment to oncology and immunology to develop biosimilars as high quality, safe, and effective treatment options to patients with cancer and autoimmune diseases.

Boehringer Ingelheim currently has two biosimilar monoclonal antibodies in late stage development: BI 695501, adalimumab biosimilar candidate to Humira® and BI 695502, bevacizumab biosimilar candidate to Avastin®.* All public information on our clinical trials is available on: http://clinicaltrials.gov/.

*Humira® is a registered trademark of AbbVie Biotechnology Ltd. in the EU/U.S. and Avastin® is a registered trademark of Genentech, Inc. (U.S.).

About Boehringer Ingelheim Pharmaceuticals, Inc.

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with 145 affiliates and about 50,000 employees. Since its founding in 1885, the family owned company has been committed to researching, developing, manufacturing and marketing novel treatments for human and veterinary medicine.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and their families. Our employees create and engage in programs that strengthen our communities. To learn more about how we make more health for more people, visit our Corporate Social Responsibility Report.

In 2015, Boehringer Ingelheim achieved net sales of about $15.8 billion (14.8 billion euros). R&D expenditure corresponds to 20.3 percent of its net sales.

For more information please visit https://www.boehringer ingelheim.us, or follow us on Twitter @BoehringerUS.

SOURCE Boehringer Ingelheim

EXHIBIT D

25 Nov 2015 | Email

Amgen's First Biosimilar Biologics License Application for ABP 501 Submitted to U.S. Food and Drug Administration

Supported by Phase 3 Studies in Moderate-to-Severe Plaque Psoriasis and Moderate-to-Severe Rheumatoid Arthritis

Amgen announced he submission of a Biologics License Application (BLA) wi h the United States (U.S) Food and Drug Administra ion (FDA) for ABP 501, a biosimilar candidate to Humira® (adalimumab). Amgen believes this submission is the first adalimumab biosimilar application submitted to the FDA and represents Amgen's first BLA submission using he 351(k) biosimilar pa hway.

"The submission of Amgen's first biosimilar application to he FDA is an exciting milestone, expanding our inflamma ion portfolio to provide additional therapeutic op ions to pa ients," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Patients with chronic inflammatory conditions are faced with a significant burden of disease requiring long-term treatment. Amgen's branded biologic medicines and biosimilars are developed and manufactured according to the same high standards, and we are committed to delivering high-quality medicines to patients with serious inflammatory diseases."

ABP 501 is a biosimilar candidate to adalimumab, an anti-TNF-α monoclonal antibody, which is approved in many countries for the treatment of various inflammatory diseases.

Amgen's BLA submission includes analytical, clinical and pharmacokinetic data. Phase 3 comparative efficacy and safety studies were conducted in both moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid ar hritis. The Phase 3 studies met heir primary endpoints showing clinical equivalence to adalimumab. Safety and immunogenicity of ABP 501 were also comparable to adalimumab. Data to support the transition of adalimumab patients to ABP 501 are included in he submission.

About ABP 501
ABP 501 is a biosimilar candidate to adalimumab, an anti-TNF-α monoclonal antibody, which is approved in many regions for the treatment of various inflammatory diseases. The ac ive ingredient of ABP 501 is an anti-TNF-α monoclonal antibody that has the same amino acid sequence as adalimumab. ABP 501 has he same pharmaceutical dosage form and strength as adalimumab (U.S.) and adalimumab (EU).

About Amgen Biosimilars
Amgen Biosimilars is committed to building upon Amgen's experience in the development and manufacturing of innova ive human herapeu ics to expand Amgen's reach to patients wi h serious illnesses. Biosimilars offer he poten ial to increase pa ient access to vital medicines, and Amgen is well positioned to leverage its 35 years of experience in biotechnology to create high-quality biosimilars and reliably supply them to patients worldwide.

For more informa ion, visit www.amgenbiosimilars.com

Comments (5) Add Comments

Kilinc, Ali
25 Nov 2015

Congrats all, to be in biosimilar market is very crucial to reach Amgens strategic goal

Camacho, Tina
25 Nov 2015

Congratulations to the team!

Simons, Susan
25 Nov 2015

Nicely done!

Khan, Mariam
25 Nov 2015

Congratulations Amgen team for submitting 1st Biosimilar BLA! This indeed is an exciting milestone on the path of increasing patient access to vital medicines through biosimilars. Thanks.

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Clark, Charles
25 Nov 2015

Congratulations on this important milestone!

EXHIBIT E

FDA accepts Sandoz application for biosimilar filgrastim

JUL 24, 2014

- *Sandoz is the first company to announce it has filed for approval of a biologic under the biosimilars pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).*
- *FDA's acceptance of Sandoz's filing is an important first step in increasing US patient access to affordable, high-quality biologics*
- *Sandoz is a global leader in biosimilars with over 50% share of the global biosimilars market [1]*

Holzkirchen, July 24, 2014 - Sandoz, a Novartis Group company, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application for filgrastim, which was filed under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

The reference product - Amgen's NEUPOGEN® - is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

"This filing acceptance represents a significant step toward making high-quality biologics more accessible in the US and we applaud FDA for its progress in making this a reality," said Mark McCamish, M.D., Ph.D., and Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz. "As they've done in Europe and other highly-regulated markets around the world, biosimilars are poised to increase US patient access to affordable, high-quality biologics, while reducing the financial burden on payers and the overall healthcare system."

Under the brand name ZARZIO®, the Sandoz biosimilar filgrastim has been marketed in more than 40 countries outside the US, generating nearly six million patient-exposure days of experience. ZARZIO is the number one biosimilar filgrastim globally and is the leading daily G-CSF in Europe with 30 percent volume market share.

Sandoz is a pioneer in biosimilars and the global market leader with over 50% share of all biosimilars approved in the highly-regulated markets of Canada, Europe, Japan and Australia. Sandoz currently markets three biosimilars outside the US; each of which occupies the #1 biosimilar position in its respective category. Sandoz biosimilars are sold in over 60 countries and have generated over 200 million patient-exposure days in experience. Sandoz also has an unrivalled pipeline with several molecules in various stages of development. Sandoz now has six molecules in Phase III clinical trials/filing preparation, more than any other company in the industry.

[1] Includes products approved in North America, Europe, Japan and Australia

Disclaimer

This press release contains forward-looking statements that can be identified by words such as "first step," "poised," "pipeline," or similar terms, or by express or implied discussions regarding potential marketing approval for biosimilar filgrastim, or regarding potential future revenues from biosimilar filgrastim.

You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that biosimilar filgrastim will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that biosimilar filgrastim will be commercially successful in the future. In particular, management's expectations regarding biosimilar filgrastim could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, the generic pharmaceuticals division of Novartis, is a global leader in the generic pharmaceutical sector. Sandoz employs over 26,500 employees and its products are available in more than 160 countries, offering a broad range of high-quality, affordable products that are no longer protected by patents. With USD 9.2 billion in sales in 2013, Sandoz has a portfolio of approximately 1,100 molecules, and holds the #1 position globally in biosimilars as well as in generic injectables, ophthalmics,

dermatology and antibiotics, complemented by leading positions in the cardiovascular, metabolism, central nervous system, pain, gastrointestinal, respiratory, and hormonal therapeutic areas. Sandoz develops, produces, and markets these medicines, as well as active pharmaceutical and biotechnological substances. Nearly half of Sandoz's portfolio is in differentiated products, which are defined as products that are more difficult to scientifically develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has benefitted from strong growth of its acquisitions, which include Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), Oriel Therapeutics (US), and Fougera Pharmaceuticals (US).

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global (http://twitter.com/Sandoz_Global).

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Neupogen® is a registered trademark of Amgen Inc.

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EXHIBIT F

APOTEX
ADVANCING GENERICS

February 17, 2015
For Immediate Release

Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Filgrastim (Grastofil™)

Company currently has two biosimilar applications (filgrastim [Neupogen®]) and pegfilgrastim [Neulasta®]) under active review by FDA

Toronto, ON – Apotex Inc., a rising competitor in the global biosimilars market, announced today that, as of February 13th, 2015, the US Food and Drug Administration has accepted for filing the company's application for Filgrastim [Grastofil™], a biosimilar version of Amgen's Neupogen®. This product has been jointly developed with Intas Pharmaceuticals Ltd.

This is the second follow-on biologic FDA submission for Apotex via the 351(k) abbreviated approval pathway created by the Biosimilar Price Competition and Innovation Act (BPCIA). Apotex also has a 351k biosimilar application for the long acting pegylated formulation of filgrastim currently under FDA review. Apotex is the only company to date to have two biosimilar filgrastim applications (pegfilgrastim and filgrastim) currently under active review by FDA. Filgrastim is used to help cancer patients taking chemotherapies fight infections and fever by boosting white blood cell counts. According to Symphony Health Solutions, Neupogen® had approximately $1-billion in sales in calendar year 2014.

"We are very pleased to be at the forefront of companies who will introduce high quality biosimilar products into the US marketplace," said Apotex President and Chief Executive Officer, Dr. Jeremy B. Desai. "Our entry into this new frontier of medicine in the United States is a watershed event in Apotex's 40 year history of providing quality, affordable medicines to patients in need around the globe," Desai added. "The benefits for patients, payers and providers from biosimilars will be significant. We are dedicated to playing a leading role in the effort to increase the American public's access to more affordable versions of these life-saving therapies and generate substantial savings for the US health care system," Desai added.

The product will be marketed in the United States by ApoBiologix®, a division of Apotex Corp.

About Apotex

Apotex is the largest Canadian owned pharmaceutical company with over 10,000 employees globally and with estimated sales of approximately $2 billion. The company's US headquarters is based in Weston, Florida. With its worldwide manufacturing sites, Apotex can produce up to 24 billion dosages per year. It produces 300 medicines in 4,000 dosages and formats that are exported to 115 countries. It has 500 products under development and will spend $2 billion over the next 10 years on research and development

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EXHIBIT G

APOTEX
ADVANCING GENERICS

December 17, 2014
For Immediate Release

Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Pegfilgrastim

Believed to be the First Company to Have a Biosimilar Filing Accepted for Review of Amgen's Neulasta®

Toronto, ON – Apotex Inc., the largest Canadian owned pharmaceutical company, announced today that the US Food and Drug Administration has accepted for filing the company's application for pegfilgrastim, a biosimilar version of Amgen's Neulasta®. The product has been jointly developed with Intas Pharmaceuticals Ltd. The application was filed under the 351(k) abbreviated approval pathway created by the Biosimilar Price Competition and Innovation Act (BPCIA).

Neulasta® is the long acting formulation of Neupogen® (filgrastim). Filgrastim is used to help cancer patients taking chemotherapies fight infections and fever by boosting white blood cell counts. Apotex believes it is the first company to have a biosimilar filing accepted for review by FDA for the long acting formulation of the product. According to IMS Health, Neulasta® had approximately $3.6 billion in sales in calendar year 2013.

"We are very pleased to be at the forefront of companies who will introduce high quality biosimilar products into the US marketplace," said Apotex President and Chief Executive Officer, Dr. Jeremy B. Desai. "Our entry into this new frontier of medicine in the United States is a watershed event in Apotex's 40 year history of providing quality, affordable medicines to patients in need around the globe," Desai added. "The benefits for patients, payers and providers from biosimilars will be significant. We are dedicated to playing a leading role in the effort to increase the American public's access to more affordable versions of these life-saving therapies and generate substantial savings for the US health care system," Desai added.

The product will be marketed in the United States by ApoBiologix®, a division of Apotex Corp.

About Apotex

Apotex is the largest Canadian owned pharmaceutical company with over 5,500 employees. Globally it has another approximately 4,500 employees with estimated sales of approximately $2 billion. The company's US headquarters is based in Weston, Florida. With its worldwide manufacturing sites, Apotex can produce up to 24 billion dosages per year. It produces 300 medicines in 4,000 dosages and formats that are exported to 115 countries. It has 500 products under development and will spend $2 billion over the next 10 years on research and development.

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EXHIBIT H

Regulatory submission for Sandoz' proposed biosimilar pegfilgrastim accepted by the FDA

NOV 18, 2015

Sandoz continues to advance its biosimilars program:

Regulatory submission for Sandoz' proposed biosimilar pegfilgrastim accepted by the FDA

- *Sandoz demonstrates commitment to oncology by seeking approval for its proposed biosimilar pegfilgrastim.*
- *Sandoz believes that the totality of evidence in its submission, including three pivotal clinical studies, will demonstrate that the proposed biosimilar is highly similar to the reference product.*
- *Proposed biosimilar pegfilgrastim filing is the second of ten regulatory filings planned over the next three years.*

Holzkirchen, November 18, 2015 - Sandoz, a Novartis company and the global leader in biosimilars, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) under the 351(k) pathway for its proposed biosimilar to Amgen's US-licensed Neulasta®

(pegfilgrastim)* - a recombinant human granulocyte colony-stimulating factor (G-CSF).

Sandoz is seeking approval for the same indication as the reference product. Pegfilgrastim is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in patients with cancer (non-myeloid) who receive chemotherapy that can cause fever and a low blood cell count (febrile neutropenia).In the US, the incidence of febrile neutropenia is estimated to be more than 60,000 a year, accounting for nearly eight cases per 1,000 cancer patients.[1] Approximately 1.6 million people per year in the US develop non-myeloid cancer.[2]

"The FDA's acceptance of our regulatory submission for biosimilar pegfilgrastim - our third biosimilar filed in the US - demonstrates our commitment to expanding patient access to biologics in the US" said Mark McCamish, M.D., Ph.D., and Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz. "If approved, physicians will have another high-quality Sandoz treatment option for patients needing granulocyte colony-stimulating factors" McCamish continued.

Sandoz believes that the totality of evidence in its submission, including three pivotal clinical trials - one pharmacokinetic and pharmacodynamic study in healthy volunteers and two comparative efficacy and safety studies in breast cancer patients - will demonstrate that the proposed biosimilar is highly similar to the reference product and therefore justifies use of biosimilar pegfilgrastim in the reference product's indication.

Sandoz has an unwavering commitment to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global market leader and currently markets three biosimilars. On 3 September 2015 Sandoz launched the first biosimilar in the United States and recently had its regulatory submission for proposed biosimilar etanercept accepted by the FDA. Sandoz has a

leading pipeline with several biosimilars across the various stages of development including five programs in Phase III clinical trials or registration preparation. The company plans to make ten planned regulatory filings over the next three years. As part of the Novartis Group, Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization.

* Neulasta is a registered trademark of Amgen Inc.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "proposed," "commitment," "seeking," "believes," "will," "planned," "potentially," "pipeline," "plans," or similar terms, or by express or implied discussions regarding potential marketing approvals for biosimilar pegfilgrastim, or regarding potential future revenues from biosimilar pegfilgrastim. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that biosimilar pegfilgrastim will be approved for sale in the United States, or at any particular time. Neither can there be any guarantee that biosimilar pegfilgrastim will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that biosimilar pegfilgrastim will be commercially successful in the future. In particular, management's expectations regarding biosimilar pegfilgrastim could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; competition in general, including potential approval

of additional versions of biosimilar pegfilgrastim; global trends toward health care cost containment, including government, industry and general public pricing pressures; unexpected litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling biosimilar pegfilgrastim; the particular prescribing preferences of physicians and patients; unexpected safety issues; unexpected manufacturing or quality issues; general economic and industry conditions, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Novartis company, is a global leader in generic pharmaceuticals and biosimilars, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe. The Sandoz portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area. The company holds leading global positions in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines.

References

[1] Caggiano V, Weiss RV, Rickert TS, Linde-Zwirble WT. Incidence, cost, and mortality of neutropenia hospitalization associated with chemotherapy. *Cancer*. 2005;103(9):1916

[2] American Cancer Society. Cancer Facts & Figures 2015. http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf (http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf) (Last accessed 19 October 2015)

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EXHIBIT I

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COHERUS BIOSCIENCES SUBMITS 351(K) BIOLOGICS LICENSE APPLICATION TO U.S. FOOD AND DRUG ADMINISTRATION FOR CHS-1701 (PEGFILGRASTIM BIOSIMILAR CANDIDATE)

REDWOOD CITY, Calif., Aug. 09, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today announced submission of the biologics license application (BLA) for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate, to U.S. FDA under the 351(k) pathway.

The BLA submission is supported by similarity data from analytical, pharmacokinetic, pharmacodynamic and immunogenicity studies comparing CHS-1701 and Neulasta.

"*The CHS-1701 BLA submission marks a significant milestone in our ongoing transition to a commercial company in a transformational year for Coherus as we continue to focus on execution of our strategic plan,*" said Denny Lanfear, President and CEO of Coherus BioSciences. "*Pegfilgrastim is the largest selling oncology product in the U.S., and CHS-1701 is the cornerstone of our oncology franchise. We believe we have a strong, competitive and order-of-entry position with this product. We anticipate our oncology portfolio to include an Avastin® biosimilar, as well as other oncology biosimilar product candidates.*"

About Coherus BioSciences, Inc.

Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities including market opportunities, expectations, goals, objectives, strategies, product pipeline, clinical studies, product development, and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to receive BLA acceptance from the FDA, obtain marketing approval for and commercialize CHS-1701. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial

potential of our biosimilar drug candidates, as well as possible patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 9, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is a registered trademark of Amgen Inc.
Avastin® is a registered trademark of Genentech.

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Coherus BioSciences, Inc.

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EXHIBIT J

Amgen And Allergan Submit Biosimilar Biologics License Application For ABP 215 To U.S. Food And Drug Administration

Supported by Phase 3 Study in Patients With Non-Squamous Non-Small Cell Lung Cancer

THOUSAND OAKS, Calif., Nov. 15, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Allergan plc. (NYSE:AGN) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ABP 215, a biosimilar candidate to Avastin® (bevacizumab). ABP 215 is the most advanced of the four oncology biosimilar medicines that Amgen and Allergan are collaborating on. The companies believe this submission is the first bevacizumab biosimilar application submitted to the FDA.

"ABP 215 is one of four oncology biosimilars in our pipeline, and today's BLA submission is an important milestone as Amgen seeks to expand our oncology portfolio," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "ABP 215 has the potential to offer an additional high-quality therapeutic option for patients diagnosed with cancer, continuing Amgen's mission of providing patients with vital medicines."

"Allergan is committed to developing safe and effective therapies in certain critical disease areas," said David Nicholson, Chief R&D Officer at Allergan. "The filing of ABP 215 is an important step forward in advancing a potential treatment option for patients with disorders susceptible to VEGF inhibition."

ABP 215 is a biosimilar candidate to bevacizumab, a recombinant immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that binds to vascular endothelial growth factor (VEGF) and inhibits the interaction of VEGF with its receptors, VEGF receptor-1 and VEGF receptor-2, thus inhibiting establishment of new blood vessels necessary for the maintenance and growth of solid tumors.

The BLA submission includes analytical, pharmacokinetic and clinical data, as well as pharmacology and toxicology data. The Phase 3 comparative efficacy, safety and immunogenicity study was conducted in adult patients with non-squamous non-small cell lung cancer (NSCLC). The Phase 3 study confirmed no clinically meaningful difference to bevacizumab in terms of efficacy, safety and immunogenicity.

Amgen and Allergan are collaborating on the development and commercialization of four oncology biosimilars. Amgen has a total of nine biosimilars in its portfolio, one which has been approved by the FDA (adalimumab-atto) and eight which are in ongoing development. Allergan is also independently developing biosimilars.

About ABP 215

ABP 215 is being developed as a biosimilar to bevacizumab, which is approved in the U.S., EU and other regions for the treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC as well as metastatic carcinoma of the colon or rectum; metastatic renal cell carcinoma; and other region-specific indications.

About the Amgen and Allergan Collaboration

In December 2011, Amgen and Allergan plc. (then Watson Pharmaceuticals, Inc.) formed a collaboration to develop and commercialize, on a worldwide basis, four oncology antibody biosimilar medicines. This collaboration reflects the shared belief that the development and commercialization of biosimilar products will not follow a pure brand or generic model, and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied therapies for patients. Under the terms of the agreement, Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products.

About Amgen Biosimilars

Amgen Biosimilars is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients with serious illnesses. Biosimilars will help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its more than 35 years of experience in biotechnology to create high quality biosimilars and reliably supply them to patients worldwide.

For more information, visit www.amgenbiosimilars.com (http://www.amgenbiosimilars.com/) and follow us on www.twitter.com/amgenbiosim (http://www.twitter.com/amgenbiosim).

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com (http://www.amgen.com/) and follow us on www.twitter.com/amgen (http://www.twitter.com/amgen).

About Allergan plc

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com (http://www.allergan.com/).

Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen project. Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

Allergan plc Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ

materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 (certain of such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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EXHIBIT K

From: <Michael.Morin@lw.com>
To: <KHummel@cravath.com>
Date: 06/13/2016 09:45 AM
Subject: RE: Amgen/AbbVie

Thanks for reaching out last night, Keith. FYI, if it's helpful on your end, we'd be ok with providing the method of use (i.e., Fischkoff, Hoffman, Banerjee, Medich, Wong) sections to our client today and can hold off on the remaining sections until tomorrow, if you need extra time to review. To be clear, we're just looking to provide the validity sections (which do not contain confidential info about ABP-501), not infringement.

Thanks,

Mike

-----Original Message-----
From: Keith Hummel [mailto:KHummel@cravath.com]
Sent: Sunday, June 12, 2016 7:26 PM
To: Morin, Mike (DC)
Subject: Re: Amgen/AbbVie

Can you give me a ring on my cell? [redacted]

Sent from my BlackBerry 10 smartphone.
Original Message
From: Michael.Morin@lw.com
Sent: Sunday, June 12, 2016 10:54 AM
To: KHummel@cravath.com
Subject: RE: Amgen/AbbVie

Sure thing. Let me know when you'd like to chat.

Thanks.

_____
From: Keith Hummel <KHummel@cravath.com>
Sent: Sunday, June 12, 2016 7:49:30 AM
To: Morin, Mike (DC)
Subject: Re: Amgen/AbbVie

Mike,

Give me a few hours to consult with the relevant people on timing. Perhaps we should talk later this afternoon.

Keith

From: <Michael.Morin@lw.com>
To: <KHummel@cravath.com>
Date: 06/12/2016 10:20 AM
Subject: Amgen/AbbVie

_____

Hey Keith, sorry to bother you on the weekend, but wanted to follow up on our discussion Friday eve. Our client (in addition to the sole designated individual) is antsy to review the validity sections of the 3(B) submission, and we also need to be able to show the validity positions to our experts. I'm trying to buy time, but am having a hard time doing so, because your validity positions clearly aren't confidential under the statute unless they contain confidential information about your product (which we don't think they do). Will you be able to confirm the absence of confidentiality of the validity sections (or send any necessary redactions) by Monday? If not, we need to get busy reviewing and redacting on our end, since the client wants it by COB Monday.

Thanks. Hope you got at least a bit of R&R.

Mike

Michael A. Morin

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