

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| # | Biosimilar                       | Applicant               | Reference Product | BLA Approval                   | U.S. Launch                   | Related BPCIA Litigation  |
|---|----------------------------------|-------------------------|-------------------|--------------------------------|-------------------------------|---|
| 1 | ZARXIO<br>(filgrastim-sndz)      | Sandoz                  | NEUPOGEN [#1]     | <a href="#">Mar. 6, 2015</a>   | <a href="#">Sept. 3, 2015</a> | <a href="#">Amgen v. Sandoz</a> ,<br>No. 14-4741 (N.D. Cal.)                    |
| 2 | INFLECTRA<br>(infliximab-dyyb)   | Celltrion               | REMICADE [#1]     | <a href="#">Apr. 5, 2016</a>   | <a href="#">Nov. 21, 2016</a> | <a href="#">Janssen v. Celltrion</a> ,<br>No. 17-11008 (D. Mass.)               |
| 3 | ERELZI<br>(etanercept-szszs)     | Sandoz                  | ENBREL [#1]       | <a href="#">Aug. 30, 2016</a>  | N/A                           | <a href="#">Immunex v. Sandoz</a> ,<br>No. 16-01118 (D.N.J.)                    |
| 4 | AMJEVITA<br>(adalimumab-atto)    | Amgen                   | HUMIRA [#1]       | <a href="#">Sept. 23, 2016</a> | <a href="#">Jan. 31, 2023</a> | <a href="#">AbbVie v. Amgen</a> ,<br>No. 16-666 (D. Del.)                       |
| 5 | RENFLEXIS<br>(infliximab-abda)   | Samsung<br>Bioepis      | REMICADE [#2]     | <a href="#">Apr. 21, 2017</a>  | <a href="#">July 24, 2017</a> | <a href="#">Janssen v. Samsung Bioepis</a> ,<br>No. 17-3524 (D. N.J.)           |
| 6 | CYLTEZO<br>(adalimumab-<br>adbm) | Boehringer<br>Ingelheim | HUMIRA [#2]       | <a href="#">Aug. 25, 2017</a>  | <a href="#">July 1, 2023</a>  | <a href="#">AbbVie v. BI</a> ,<br>No. 17-1065 (D. Del.)                         |
| 7 | MVASI<br>(bevacizumab-<br>awwb)  | Amgen                   | AVASTIN [#1]      | <a href="#">Sept. 14, 2017</a> | <a href="#">July 19, 2019</a> | <a href="#">Genentech v. Amgen</a> ,<br>Nos. 17-1407, 17-1471, 19-602 (D. Del.) |
| 8 | OGIVRI<br>(trastuzumab-dkst)     | Mylan                   | HERCEPTIN [#1]    | <a href="#">Dec. 1, 2017</a>   | <a href="#">Dec. 2, 2019</a>  | N/A   |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                           | Applicant | Reference Product        | BLA Approval                  | U.S. Launch                   | Related BPCIA Litigation   |
|----|--------------------------------------|-----------|--------------------------|-------------------------------|-------------------------------|--|
| 9  | IXIFI<br>(infliximab-qbtx)           | Pfizer    | REMICADE [#3]            | <a href="#">Dec. 13, 2017</a> | N/A                           | N/A  |
| 10 | RETACRIT<br>(epoetin alfa-epbx)      | Hospira   | EPOGEN/<br>PROCRIPT [#1] | <a href="#">May 15, 2018</a>  | <a href="#">Nov. 12, 2018</a> | <a href="#">Amgen v. Hospira</a> ,<br>No. 15-839 (D. Del.)                       |
| 11 | FULPHILA<br>(pegfilgrastim-<br>jmdb) | Mylan     | NEULASTA [#1]            | <a href="#">June 4, 2018</a>  | <a href="#">July 26, 2018</a> | <a href="#">Amgen v. Mylan</a> ,<br>No. 17-1235 (W.D. Pa.)                       |
| 12 | NIVESTYM<br>(filgrastim-aafi)        | Pfizer    | NEUPOGEN [#2]            | <a href="#">July 20, 2018</a> | <a href="#">Oct. 1, 2018</a>  | <a href="#">Amgen v. Hospira</a> ,<br>Nos. 18-1064, 20-561 (D. Del.)             |
| 13 | HYRIMOZ<br>(adalimumab-<br>adaz)     | Sandoz    | HUMIRA [#3]              | <a href="#">Oct. 30, 2018</a> | <a href="#">July 2023</a>     | <a href="#">AbbVie v. Sandoz</a> ,<br>No. 18-12668 (D. N.J.)                     |
| 14 | UDENYCA<br>(pegfilgrastim-<br>cbqv)  | Coherus   | NEULASTA [#2]            | <a href="#">Nov. 2, 2018</a>  | <a href="#">Jan. 3, 2019</a>  | <a href="#">Amgen v. Coherus</a> ,<br>No. 17-546 (D. Del.)                       |
| 15 | TRUXIMA<br>(rituximab-abbs)          | Celltrion | RITUXAN [#1]             | <a href="#">Nov. 28, 2018</a> | <a href="#">Nov. 11, 2019</a> | <a href="#">Genentech v. Celltrion</a> ,<br>Nos. 18-574, 18-11553 (D. N.J.)      |
| 16 | HERZUMA<br>(trastuzumab-<br>pkrb)    | Celltrion | HERCEPTIN [#2]           | <a href="#">Dec. 14, 2018</a> | <a href="#">Mar. 16, 2020</a> | <a href="#">Genentech v. Celltrion</a> ,<br>Nos. 18-00095, 18-01025<br>(D. Del.) |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                      | Applicant       | Reference Product | BLA Approval                  | U.S. Launch                   | Related BPCIA Litigation  |
|----|---------------------------------|-----------------|-------------------|-------------------------------|-------------------------------|---|
| 17 | ONTRUZANT<br>(trastuzumab-dttb) | Samsung Bioepis | HERCEPTIN [#3]    | <a href="#">Jan. 18, 2019</a> | <a href="#">Apr. 15, 2020</a> | <a href="#">Genentech v. Samsung Bioepis</a> ,<br>No. 18-1363 (D. Del.) |
| 18 | TRAZIMERA<br>(trastuzumab-qyyp) | Pfizer          | HERCEPTIN [#4]    | <a href="#">Mar. 11, 2019</a> | <a href="#">Feb. 15, 2020</a> | <a href="#">Genentech v. Pfizer</a> ,<br>No. 17-1672 (D. Del.)          |
| 19 | ETICOVO<br>(etanercept-ykro)    | Samsung Bioepis | ENBREL [#2]       | <a href="#">Apr. 25, 2019</a> | N/A                           | <a href="#">Immunex v. Samsung Bioepis</a> ,<br>No. 19-11755 (D. N.J.)  |
| 20 | KANJINTI<br>(trastuzumab-anns)  | Amgen           | HERCEPTIN [#5]    | <a href="#">June 13, 2019</a> | <a href="#">July 19, 2019</a> | <a href="#">Genentech v. Amgen</a> ,<br>No. 18-924 (D. Del.)            |
| 21 | ZIRABEV<br>(bevacizumab-bvzr)   | Pfizer          | AVASTIN [#2]      | <a href="#">June 28, 2019</a> | <a href="#">Dec. 31, 2019</a> | <a href="#">Genentech v. Pfizer</a> ,<br>No. 19-638 (D. Del.)           |
| 22 | RUXIENCE<br>(rituximab-pvvr)    | Pfizer          | RITUXAN [#2]      | <a href="#">July 23, 2019</a> | <a href="#">Jan. 23, 2020</a> | N/A   |
| 23 | HADLIMA<br>(adalimumab-bwwd)    | Samsung Bioepis | HUMIRA [#4]       | <a href="#">July 23, 2019</a> | <a href="#">July 1, 2023</a>  | N/A   |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                         | Applicant | Reference Product | BLA Approval                  | U.S. Launch                   | Related BPCIA Litigation                                     |
|----|------------------------------------|-----------|-------------------|-------------------------------|-------------------------------|--|
| 24 | ZIEXTENZO<br>(pegfilgrastim-bmez)  | Sandoz    | NEULASTA [#3]     | <a href="#">Nov. 4, 2019</a>  | <a href="#">Nov. 15, 2019</a> | <a href="#">Amgen v. Sandoz</a> ,<br>No. 16-2581 (N.D. Cal.) |
| 25 | ABRILADA<br>(adalimumab-afzb)      | Pfizer    | HUMIRA [#5]       | <a href="#">Nov. 15, 2019</a> | October 2023                  | N/A  |
| 26 | AVSOLA<br>(infliximab-axxq)        | Amgen     | REMICADE [#4]     | <a href="#">Dec. 6, 2019</a>  | July 2020                     | N/A  |
| 27 | NYVEPRIA<br>(pegfilgrastim-apgf)   | Pfizer    | NEULASTA [#4]     | <a href="#">June 10, 2020</a> | Late 2020 or<br>early 2021    | <a href="#">Amgen v. Hospira</a> ,<br>No. 20-210 (D. Del.)   |
| 28 | HULIO<br>(adalimumab-fkjp)         | Mylan     | HUMIRA [#6]       | <a href="#">July 6, 2020</a>  | <a href="#">July 3, 2023</a>  | N/A  |
| 29 | RIABNI<br>(rituximab-arrx)         | Amgen     | RITUXAN [#3]      | Dec. 17, 2020                 | Jan. 12, 2021                 | N/A  |
| 30 | SEMGLEE<br>(insulin glargine-yfgn) | Viartis   | LANTUS [#1]       | <a href="#">July 28, 2021</a> | Nov. 16, 2021                 | N/A  |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                           | Applicant                     | Reference Product | BLA Approval                   | U.S. Launch                   | Related BPCIA Litigation |
|----|--------------------------------------|-------------------------------|-------------------|--------------------------------|-------------------------------|--------------------------|
| 31 | BYOOVIZ<br>(ranibizumab-nuna)        | Biogen/<br>Samsung<br>Bioepis | LUCENTIS [#1]     | <a href="#">Sept. 20, 2021</a> | <a href="#">June 2, 2022</a>  | N/A                      |
| 32 | YUSIMRY<br>(adalimumab-aqvh)         | Coherus                       | HUMIRA [#7]       | <a href="#">Dec. 17, 2021</a>  | <a href="#">July 3, 2023</a>  | N/A                      |
| 33 | REZVOGLAR<br>(insulin glargine-aglr) | Eli Lilly                     | LANTUS [#2]       | Dec. 20, 2021                  | April 1, 2023                 | N/A                      |
| 34 | RELEUKO<br>(filgrastim-ayow)         | Amneal/Kash<br>iv             | NEUPOGEN [#3]     | <a href="#">Feb. 25, 2022</a>  | <a href="#">Nov. 22, 2022</a> | N/A                      |
| 35 | ALYMSYS<br>(bevacizumab-maly)        | Amneal/<br>mAbxience          | AVASTIN [#3]      | <a href="#">Apr. 13, 2022</a>  | <a href="#">Oct. 3, 2022</a>  | N/A                      |
| 36 | FYLNETRA<br>(pegfilgrastim-pbbk)     | Amneal/Kash<br>iv             | NEULASTA [#5]     | <a href="#">May 26, 2022</a>   | <a href="#">May 16, 2023</a>  | N/A                      |
| 37 | CIMERLI<br>(ranibizumab-eqrn)        | Coherus                       | LUCENTIS [#2]     | <a href="#">Aug. 2, 2022</a>   | <a href="#">Oct. 3, 2022</a>  | N/A                      |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                        | Applicant      | Reference Product | BLA Approval                   | U.S. Launch                   | Related BPCIA Litigation   |
|----|-----------------------------------|----------------|-------------------|--------------------------------|-------------------------------|--|
| 38 | STIMUFEND<br>(pegfilgrastim-fpgk) | Fresenius Kabi | NEULASTA [#6]     | <a href="#">Sept. 1, 2022</a>  | <a href="#">Feb. 16, 2023</a> | N/A  |
| 39 | VEGZELMA<br>(bevacizumab-adcd)    | Celltrion      | AVASTIN [#4]      | <a href="#">Sept. 27, 2022</a> | <a href="#">Apr. 17, 2023</a> | N/A  |
| 40 | IDACIO<br>(adalimumab-aacf)       | Fresenius Kabi | HUMIRA [#8]       | <a href="#">Dec. 13, 2022</a>  | <a href="#">July 3, 2023</a>  | N/A  |
| 41 | YUFLYMA<br>(adalimumab-aaty)      | Celltrion      | HUMIRA [#9]       | <a href="#">May 23, 2023</a>   | <a href="#">July 2, 2023</a>  | N/A  |
| 42 | TYRUKO<br>(natalizumab-sztn)      | Sandoz         | TYSABRI [#1]      | <a href="#">Aug. 24, 2023</a>  | Nov. 17, 2025                 | <a href="#">Biogen v. Sandoz</a> ,<br>No. 1:22-cv-1190 (D. Del.)         |
| 43 | TOFIDENCE<br>(tocilizumab-bavi)   | Biogen         | ACTEMRA [#1]      | <a href="#">Sept. 29, 2023</a> | <a href="#">May 6, 2024</a>   | <a href="#">Genentech v. Biogen</a> ,<br>No. 1:23-cv-11573<br>(D. Mass.) |
| 44 | ZYMFENTRA<br>(infliximab-dyyb)    | Celltrion      | REMICADE [#5]     | <a href="#">Oct. 23, 2023</a>  | Mar. 18, 2024                 | N/A  |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                     | Applicant                 | Reference Product | BLA Approval                  | U.S. Launch                   | Related BPCIA Litigation   |
|----|--------------------------------|---------------------------|-------------------|-------------------------------|-------------------------------|--|
| 45 | WEZLANA<br>(ustekinumab-aaub)  | Amgen                     | STELARA [#1]      | <a href="#">Oct. 31, 2023</a> | Jan. 1, 2025                  | <a href="#">Janssen Biotech v. Amgen</a> ,<br>No. 1-22-cv-1549<br>(D. Del.)                          |
| 46 | AVZIVI<br>(bevacizumab-tnjn)   | Bio-Thera Solutions, Ltd. | AVASTIN [#5]      | <a href="#">Dec. 6, 2023</a>  | N/A                           | N/A  |
| 47 | SIMLANDI<br>(adalimumab-ryvk)  | Alvotech                  | HUMIRA [#10]      | <a href="#">Feb. 23, 2024</a> | <a href="#">May 20, 2024</a>  | <a href="#">Abbvie v. Alvotech</a> ,<br>Nos. 21-2258, 21-2899 (N.D. Ill.); No. 2-21-00265 (E.D. Va.) |
| 48 | TYENNE<br>(tocilizumab-aazg)   | Fresenius                 | ACTEMRA [#2]      | <a href="#">Mar. 5, 2024</a>  | <a href="#">Apr. 15, 2024</a> | N/A  |
| 49 | WYOST<br>(denosumab-bddz)      | Sandoz                    | XGEVA [#1]        | <a href="#">Mar. 5, 2024</a>  | <a href="#">June 2, 2025</a>  | <a href="#">Amgen v. Sandoz</a> ,<br>No. 2-23-cv-02406 (D.N.J.)                                      |
| 50 | JUBBONTI<br>(denosumab-bddz)   | Sandoz                    | PROLIA [#1]       | <a href="#">Mar. 5, 2024</a>  | <a href="#">June 2, 2025</a>  | <a href="#">Amgen v. Sandoz</a> ,<br>No. 2-23-cv-02406 (D.N.J.)                                      |
| 51 | SELARSDI<br>(ustekinumab-aekn) | Alvotech/<br>Teva         | STELARA [#2]      | <a href="#">Apr. 16, 2024</a> | <a href="#">Feb. 21, 2025</a> | N/A  |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                     | Applicant                  | Reference Product | BLA Approval                  | U.S. Launch                  | Related BPCIA Litigation   |
|----|--------------------------------|----------------------------|-------------------|-------------------------------|------------------------------|--|
| 52 | HERCESSI<br>(trastuzumab-strf) | Accord BioPharma           | HERCEPTIN [#6]    | <a href="#">Apr. 25, 2024</a> | <a href="#">Dec. 2, 2024</a> | N/A  |
| 53 | YESAFILI<br>(afibercept-jbyf)  | Biocon Biologics           | EYLEA [#1]        | <a href="#">May 20, 2024</a>  | N/A                          | <a href="#">Regeneron v. Mylan</a> ,<br>No. 1-22-cv-00061 (N.D. W. Va.)                          |
| 54 | OPUVIZ<br>(alibercept-yszy)    | Samsung Bioepis            | EYLEA [#2]        | <a href="#">May 20, 2024</a>  | N/A                          | <a href="#">Regeneron v. Samsung Bioepis</a> ,<br>Nos. 1-23-cv-00094, 1-23-cv-00106 (N.D. W.Va.) |
| 55 | BKEMV<br>(eculizumab-aeab)     | Amgen                      | SOLIRIS [#1]      | <a href="#">May 28, 2024</a>  | Mar. 5, 2025                 | None   |
| 56 | AHZANTIVE<br>(afibercept-mrbb) | Formycon                   | EYLEA [#3]        | <a href="#">June 28, 2024</a> | N/A                          | <a href="#">Regeneron v. Formycon</a> ,<br>1-23-cv-00097 (N.D. W. Va.)                           |
| 57 | NYPOZI<br>(filgrastim-txid)    | Tanvex BioPharma USA, Inc. | NEUPOGEN [#4]     | <a href="#">June 28, 2024</a> | N/A                          | <a href="#">Amgen v. Tanvex</a> , No. 19-1374 (S.D. Cal.)  |
| 58 | PYZCHIVA<br>(ustekinumab-ttwe) | Samsung Bioepis            | STELARA [#3]      | <a href="#">June 28, 2024</a> | Feb. 24, 2025                | N/A  |
| 59 | EPYSQLI<br>(eculizumab-aagh)   | Samsung Bioepis            | SOLIRIS [#2]      | <a href="#">July 19, 2024</a> | <a href="#">Apr. 7, 2025</a> | <a href="#">Alexion v. Samsung Bioepis</a> ,<br>No. 1-24-cv-00005 (D. Del.)                      |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                     | Applicant             | Reference Product | BLA Approval                   | U.S. Launch                   | Related BPCIA Litigation  |
|----|--------------------------------|-----------------------|-------------------|--------------------------------|-------------------------------|---|
| 60 | ENZEEVU<br>(afibercept-abzv)   | Sandoz                | EYLEA [#4]        | <a href="#">Aug. 9, 2024</a>   | N/A                           | <a href="#">Regeneron v. Sandoz</a> ,<br>No. 1-24-cv-00085 (N.D. W.Va.)                 |
| 61 | PAVBLU<br>(afibercept-ayyh)    | Amgen                 | EYLEA [#5]        | <a href="#">Aug. 23, 2024</a>  | <a href="#">Oct. 30, 2024</a> | <a href="#">Regeneron v. Amgen</a> ,<br>Nos. 1-24-cv-00039, 1-25-cv-00074 (N.D. W. Va.) |
| 62 | OTULFI<br>(ustekinumab-aauz)   | Fresenius Kabi        | STELARA [#4]      | <a href="#">Sept. 27, 2024</a> | <a href="#">Mar. 3, 2025</a>  | N/A   |
| 63 | IMULDOSA<br>(ustekinumab-srlf) | Accord Biopharma      | STELARA (#5)      | <a href="#">Oct. 10, 2024</a>  | Aug. 18, 2025                 | N/A   |
| 64 | YESINTEK<br>(ustekinumab-kfce) | Biocon Biologics Ltd. | STELARA [#6]      | <a href="#">Nov. 29, 2024</a>  | <a href="#">Feb. 24, 2025</a> | N/A   |
| 65 | STEQEYMA<br>(ustekinumab-stba) | Celltrion             | STELARA [#7]      | <a href="#">Dec. 17, 2024</a>  | <a href="#">Mar. 12, 2025</a> | N/A   |
| 66 | AVTOZMA<br>(tocilizumab-anoh)  | Celltrion             | ACTEMRA [#3]      | <a href="#">Jan. 24, 2025</a>  | Oct. 2, 2025                  | N/A   |
| 67 | OSPOMYV<br>(denosumab-dssb)    | Samsung Bioepis       | PROLIA [#2]       | <a href="#">Feb. 13, 2025</a>  | N/A                           | <a href="#">Amgen v. Samsung Bioepis</a> ,<br>No. 1-24-cv-08417 (D.N.J.)                |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                    | Applicant       | Reference Product | BLA Approval                  | U.S. Launch  | Related BPCIA Litigation  |
|----|-------------------------------|-----------------|-------------------|-------------------------------|--------------|---|
| 68 | XBRYK (denosumab-dssb)        | Samsung Bioepis | XGEVA [#2]        | <a href="#">Feb. 13, 2025</a> | N/A          | <a href="#">Amgen v. Samsung Bioepis</a> , No. 1-24-cv-08417 (D.N.J.)       |
| 69 | MERILOG (insulin aspart-sjzz) | Sanofi Aventis  | NOVOLOG [#1]      | <a href="#">Feb. 14, 2025</a> | N/A          | N/A   |
| 70 | STOBOCLO (denosumab-bnwo)     | Celltrion       | PROLIA [#3]       | Feb. 28, 2025                 | July 7, 2025 | <a href="#">Amgen v. Celltrion</a> , No. 1:24-cv-06497 (D. N.J.)            |
| 71 | OSENVELT (denosumab-bnwo)     | Celltrion       | XGEVA [#3]        | Feb. 28, 2025                 | July 7, 2025 | <a href="#">Amgen v. Celltrion</a> , No. 1:24-cv-06497 (D. N.J.)            |
| 72 | OMLYCLO (omalizumab-igec)     | Celltrion       | XOLAIR [#1]       | <a href="#">Mar. 7, 2025</a>  | N/A          | N/A   |
| 71 | BOMYNATA (denosumab-bnht)     | Fresenius       | XGEVA [#4]        | Mar. 25, 2025                 | July 1, 2025 | <a href="#">Amgen v. Fresenius Kabi USA, LLC</a> , No. 1-25-01080 (D. N.J.) |
| 72 | CONEXXENCE (denosumab-bnht)   | Fresenius       | PROLIA [#4]       | Mar. 25, 2025                 | July 1, 2025 | <a href="#">Amgen v. Fresenius Kabi USA, LLC</a> , No. 1-25-01080 (D. N.J.) |
| 73 | JOBEVNE (bevacizumab-nwgd)    | Biocon          | AVASTIN [#6]      | <a href="#">Apr. 9, 2025</a>  | N/A          | N/A   |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                   | Applicant                | Reference Product | BLA Approval                   | U.S. Launch                  | Related BPCIA Litigation   |
|----|------------------------------|--------------------------|-------------------|--------------------------------|------------------------------|--|
| 74 | STARJEMZA (ustekinumab-hmny) | Bio-Thera Solutions      | STELARA [#8]      | May 22, 2025                   | <a href="#">Nov. 6, 2025</a> | N/A  |
| 75 | KIRSTY (insulin-aspart-xjhz) | Biocon                   | NOVOLOG [#2]      | <a href="#">July 15, 2025</a>  | N/A                          | N/A  |
| 76 | BILDYOS (denosumab-nxxp)     | Shanghai Henlius Biotech | XGEVA [#5]        | <a href="#">Aug. 29, 2025</a>  | N/A                          | <a href="#">Amgen v. Shanghai Henlius Biotech, Inc.</a> , No. 1:25-12160 (D. N.J.) |
| 77 | BILPREVDA (denosumab-kyqq)   | Shanghai Henlius Biotech | PROLIA [#5]       | <a href="#">Aug. 29, 2025</a>  | N/A                          | <a href="#">Amgen v. Shanghai Henlius Biotech, Inc.</a> , No. 1:25-12160 (D. N.J.) |
| 78 | AUKELSO (denosumab-kyqq)     | Biocon                   | XGEVA [#6]        | <a href="#">Sept. 16, 2025</a> | N/A                          | <a href="#">Amgen v. Biocon Biologics, Inc.</a> , No. 1:25-cv-143358 (D. N.J.)     |
| 79 | BOSAYA (denosumab-kyqq)      | Biocon                   | PROLIA [#6]       | <a href="#">Sept. 16, 2025</a> | N/A                          | <a href="#">Amgen v. Biocon Biologics, Inc.</a> , No. 1:25-cv-143358 (D. N.J.)     |
| 78 | XTRENBO (denosumab-qdbe)     | Hikma                    | XGEVA [#7]        | <a href="#">Sept. 26, 2025</a> | N/A                          | <a href="#">Amgen v. Hikma</a> , No. 1:25-cv-143358 (D. N.J.)                      |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                      | Applicant                | Reference Product | BLA Approval                   | U.S. Launch | Related BPCIA Litigation  |
|----|---------------------------------|--------------------------|-------------------|--------------------------------|-------------|---|
| 79 | ENOBY<br>(denosumab-qdbe)       | Hikma                    | PROLIA [#7]       | <a href="#">Sept. 26, 2025</a> | N/A         | <a href="#">Amgen v. Hikma</a> , No. 1:25-cv-143358 (D. N.J.)                           |
| 80 | EYDENZELT<br>(aflibercept-boav) | Celltrion                | EYLEA [#6]        | <a href="#">Oct. 2, 2025</a>   | N/A         | <a href="#">Regeneron v. Celltrion</a> , Nos. 1:23-cv-00089, 1:24-cv-00053 (N.D.W. Va.) |
| 81 | POHERDY<br>(pertuzumab-dpzb)    | Shanghai Henlius Biotech | PERJETA [#1]      | <a href="#">Nov. 13, 2025</a>  | N/A         | <a href="#">Genentech v. Shanghai Henlius Biotech</a> , No. 2:25-cv-14648 (D. N.J.)     |
| 82 | JUBEREQ<br>(denosumab-desu)     | Accord Biopharma, Inc.   | XGEVA [#8]        | <a href="#">Nov. 20, 2025</a>  | N/A         | <a href="#">Amgen v. Accord Biopharma, Inc.</a> , No. 1-25-cv-01305 (D.N.J.)            |
| 83 | OSVYRTI<br>(denosumab-desu)     | Accord Biopharma, Inc.   | PROLIA [#8]       | <a href="#">Nov. 20, 2025</a>  | N/A         | <a href="#">Amgen v. Accord Biopharma, Inc.</a> , No. 1-25-cv-01305 (D.N.J.)            |
| 84 | NUFYMCO<br>(randibizumab-leyk)  | Formycon AG              | LUCENTIS [#3]     | Dec. 18, 2025                  | N/A         | N/A   |
| 85 | OZILTUS<br>(denosumab-mobz)     | Amneal                   | XGEVA [#9]        | <a href="#">Dec. 22, 2025</a>  | N/A         | <a href="#">Amgen Inc. et al. v. Amneal Pharms LLC et al.</a> , 1-25-17278 (D. N.J.)    |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

| #  | Biosimilar                        | Applicant            | Reference Product | BLA Approval                  | U.S. Launch | Related BPCIA Litigation   |
|----|-----------------------------------|----------------------|-------------------|-------------------------------|-------------|--|
| 86 | BONCRESA (denosumab-mobz)         | Amneal               | PROLIA [#9]       | <a href="#">Dec. 22, 2025</a> | N/A         | <a href="#">Amgen Inc. et al. v. Amneal Pharms LLC et al.</a> , 1-25-17278 (D. N.J.)                 |
| 86 | FILKRI (filgrastim-laha)          | Accord Biopharma     | NEUPOGEN [#5]     | <a href="#">Jan. 15, 2026</a> | N/A         | N/A  |
| 87 | PONLIMSI (denosumab-abed)         | Teva                 | PROLIA [#10]      | Mar. 30, 2026                 | N/A         | N/A  |
| 88 | LANGLARA (insuline glargine-aldy) | Sunshine Lake Pharma | LANTUS [#3]       | Apr. 29, 2026                 | N/A         | N/A  |
| 89 | ENNUMO (pegfilgrastim-aldy)       | Accord BioPharma     | NEULASTA [#8]     | Apr. 7, 2026                  | N/A         | N/A  |
| 89 | IMMGOLIS (golimumab-sldi)         | Accord BioPharma     | SIMPONI [#1]      | May 15, 2026                  | N/A         | <a href="#">Janssen Biotech, Inc. et al v. Accord BioPharma, Inc. et al.</a> 1:26-CV-00222 (D. Del.) |
| 90 | IMMGOLIS INTRI (golimumab-sldi)   | Accord BioPharma     | SIMPONI ARIA [#1] | May 15, 2026                  | N/A         | <a href="#">Janssen Biotech, Inc. et al v. Accord BioPharma, Inc. et al.</a> 1:26-CV-00222 (D. Del.) |

## Big Molecule Watch Biosimilar FDA Approvals Tracker

---

Last Updated: May 18, 2026