プレスリリース
本資料は医薬品のプロモーションや宣伝広告を目的とするものではありません。

2026 年 11 月 6 日

再発・難治性多発性骨髄腫の治療薬として リンボセルタマブの製造販売承認を申請

リジェネロン・ジャパン株式会社は、本日、3 つ以上の前治療歴を有し、かつ疾患進行が確認された再発・難治性多発性骨髄腫の成人患者に対する治療薬として、リンボセルタマブ（linvoseltamab）の日本国内における製造販売承認を申請しました。この申請は、再発・難治性多発性骨髄腫におけるリンボセルタマブの有効性、安全性および忍容性を評価する国際ピボタル試験「LINKER-MM1」の結果に基づくものです。リンボセルタマブは、多発性骨髄腫細胞上に発現する B 細胞成熟抗原（BCMA）と T 細胞上に発現する CD3 の両方に結合する二重特異性抗体で、T 細胞の活性化と腫瘍細胞の死滅を促進します。

多発性骨髄腫は、がん化した形質細胞（骨髄腫細胞）が増殖し、骨髄内の正常な血液細胞を排除するとともに、他の組織にも浸潤し、深刻な臓器障害などを引き起こす疾患です。治療法の進歩により、がんの進行を遅らせることは可能ですが、多くの場合さらなる治療が必要となります。日本における多発性骨髄腫の年間罹患数は 7,938 例（男性 4,292 例、女性 3,646 例）です*。

リンボセルタマブは、再発・難治性多発性骨髄腫の成人患者に対する治療薬として、2025 年 4 月に欧州委員会（EC）より、2025 年 7 月に米食品医薬品局（FDA）より、承認を受けています。

*国立がん研究センターがん情報サービス（2023 年）

血液疾患領域におけるリジェネロンについて

リジェネロンは、30 年以上にわたって培った生物学の知見と、VelociSuite®などの独自技術を活用し、さまざまな血液がんや希少血液疾患の治療薬の開発に取り組んでいます。

血液がんにおいては、単剤療法およびさまざまな併用療法として臨床開発が進められている二重特異性抗体や、新たな治療モダリティの研究に注力しています。これらを組み合わせることで、カスタマイズされ、潜在的なシナジー効果を有する、独自の柔軟ながん治療法を開発しています。

新たな希少血液疾患の治療法を開発するために、抗体医薬、遺伝子編集技術、遺伝子ノックアウト技術などの分野で、研究や共同研究を行っています。また、異常タンパク質を減らしたり、疾患を引き起こす細胞シグナル伝達を阻害したりするための RNA アプローチの研究も進めています。

リジェネロンについて

リジェネロンは、重篤な疾患をもつ患者さんの生活や人生を大きく変える治療薬の創薬、開発、事業化に取り組むバイオ医薬品のリーディングカンパニーです。リジェネロンは、医師であり、

科学者でもある創設者が35年以上にわたって経営を担い、サイエンスから医薬を創り出す独自の能力を培ってきました。その結果、多くの新薬が承認され、開発中の医薬品候補も多数にのぼります。そして、これらの医薬品のほとんどが、リジェネロンの自社研究所で創薬、開発されたものです。リジェネロンの医薬品とパイプライン品目は、眼疾患、アレルギー・炎症性疾患、がん、循環器・代謝性疾患、神経系疾患、血液疾患、感染症および希少疾患の患者さんのアンメットニーズに応えることを目的としています。

リジェネロンは、VelociSuite®などの独自技術を使って、従来の医薬品開発プロセスの迅速化と改善に取り組んでいます。その一つであるVelocImmune®は、独自の遺伝子改変ヒト化マウスを用いて、最適化された完全ヒト型抗体や二重特異性抗体を作製する技術です。また、世界最大規模の遺伝子シーケンシングを進めるリジェネロン・ジェネティクスセンターなど、多くの研究イチシアティブに取り組んでいます。

日本におけるリジェネロンについて

リジェネロンは、2023 年 10 月に「デュピクセント®」（一般名：デュピルマブ（遺伝子組換え））のコ・プロモーションを通じて、日本での事業を開始しました。2024 年 6 月には、抗悪性腫瘍剤「リブタヨ®」（一般名：セミプリマブ（遺伝子組換え））の日本における製造販売承認を承継して、同製品の情報提供活動を開始しました。

サイエンスから医薬を創り出し、重篤な疾患に苦しむ患者さんの人生を変える、というミッションを実現すべく、今後も日本における事業の拡充に努めます。詳しくは www.regeneron.co.jp をご覧ください。

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Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. and its subsidiaries (collectively, "Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation DB-OTO (INN: lunsotogene parvec); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including DB-OTO for the treatment of biallelic OTOF variant-associated hearing loss in Japan as discussed in this press release; uncertainty of the utilization, market acceptance, and/or commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as DB-OTO); the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as DB-OTO) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy, including in connection with Regeneron's April 2026 agreements with the U.S. government; other changes in laws, regulations, and policies affecting the healthcare industry; competing products and product candidates (including biosimilar products) that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2025 and its Form 10-Q for the quarterly period ended March 31, 2026. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).