



Alvotech and Dr. Reddy's enter into collaboration for commercialization of AVT03 (denosumab), a biosimilar candidate to Prolia® & Xgeva® in the U.S., Europe and UK

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- *Dr. Reddy's gets exclusive commercialization rights in the United States (U.S.) as well as semi-exclusive rights in Europe and United Kingdom (UK)*
- *Alvotech will be responsible for development and manufacture of the product*

HYDERABAD, India and REYKJAVIK, Iceland, May 21, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide ("Alvotech"), and Dr. Reddy's Laboratories SA, wholly-owned subsidiary of Dr. Reddy's Laboratories Ltd., (BSE: 500124 | NSE: DRREDDY | NYSE: RDY | NSEIFSC: DRREDDY, along with its subsidiaries hereafter referred to as "Dr. Reddy's"), today announced that the companies have entered into a license and supply agreement for the commercialization of AVT03, Alvotech's biosimilar candidate to Prolia® and Xgeva® (denosumab). The collaboration combines Dr. Reddy's global commercial presence with Alvotech's proven capabilities in developing biosimilars for markets worldwide.

Prolia® and Xgeva® are indicated for the treatment of various diseases including osteoporosis in postmenopausal women and prevention of skeletal-related events in adults with advanced malignancies*.

Alvotech will be responsible for development and manufacturing of the product. Dr. Reddy's will be responsible for registration and commercialization of the product in the applicable markets. The license and supply agreement includes an upfront payment to Alvotech, with additional payments upon certain regulatory and commercialization milestones as well as sales-based payments. Dr. Reddy's commercialization rights are exclusive for the U.S., and semi-exclusive for Europe and the UK.

Erez Israeli, Chief Executive Officer of Dr. Reddy's, said: "We are pleased to collaborate with Alvotech to make this denosumab biosimilar available to patients in the U.S., Europe and UK. Over the years, we have created a portfolio of biosimilar products, which are marketed in several emerging markets. Most recently, we launched bevacizumab, our first biosimilar in the UK. This strategic collaboration augments our growing portfolio of biosimilar offerings, and progresses our biosimilar journey further into the highly regulated markets. We look forward to leveraging our strong commercial capabilities in these markets to ensure patients receive access to best-in-class therapies and affordable treatment options."

"We are proud to announce this new strategic partnership, that will enable us to increase the availability of cost-effective, critical biologic medications across multiple markets worldwide," said Robert Wessman, Chairman and CEO of Alvotech. "Dr. Reddy's shares our commitment to provide better access to safe and effective biologics. Biosimilars play an increasingly important role in global healthcare systems, offering broader access to best-in-class therapies. Combining our resources will ensure that patients globally can be better served."

About AVT03*

AVT03 is a human monoclonal antibody and biosimilar candidate to Prolia® and Xgeva®, which are both denosumab but in different presentations. Prolia® is indicated for the treatment of osteoporosis in postmenopausal women and for bone loss in adult men and women at increased risk of fracture [1]. Xgeva® is indicated for prevention of skeletal-related events such as pathological fractures in adults with advanced malignancies involving bone [2]. In January 2024, Alvotech announced positive top-line results from a pharmacokinetic (PK) study which assessed the pharmacokinetics, safety, and tolerability of AVT03 compared to Prolia® in healthy adult subjects [3]. A confirmatory efficacy and safety study for AVT03 in patients is currently underway, as well as a PK study comparing AVT03 to Xgeva® in healthy adult subjects. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

**Does not include full list of indications, please refer to the PIs linked below for complete information.*

References

1. Amgen Inc. Prolia® (Denosumab): Prescribing Information. Available from: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_pi.pdf
2. Amgen Inc. Xgeva® (Denosumab): Prescribing Information. Available from: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/xgeva/xgeva_pi.pdf
3. AVT03 with Prolia in Healthy Male Subjects: Study Overview. Available from: <https://clinicaltrials.gov/study/NCT05126784>

Use of trademarks

Prolia® and Xgeva® are registered trademarks of Amgen Inc.

About Dr. Reddy's Laboratories Ltd:

Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil, and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first

Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance.

Over the last 25 years, our Biologics team has developed into a fully integrated organization with robust capabilities in the development, manufacture and commercialization of a range of biosimilar products in oncology and immunology. We have a current portfolio of six commercial products marketed in India, with some products marketed in more than 25 other countries. In addition, we have several products in the pipeline in oncology and auto-immune diseases in various stages of development for global launches across regulated as well as emerging markets. We are also ramping up manufacturing capacity to support our global expansion plans. In 2024, we launched our first biosimilar in the United Kingdom, Versavo® (biosimilar bevacizumab). This follows our launch of pegfilgrastim in the U.S and Europe through our partner. Our biosimilars business has a key role to play in driving both near-term and long-term growth.

For more information, log on to: www.drreddys.com.

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Dr. Reddy's Disclaimer

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About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline contains eight biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa, and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

For more information visit Alvotech's [investor portal](#), and [website](#) or follow Alvotech on social media on [LinkedIn](#), [Facebook](#), [Instagram](#), [X](#) and [YouTube](#).

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Alvotech Forward Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech and may include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events,

regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expect”, “intend”, “will”, “estimate”, “anticipate”, “believe”, “predict”, “potential”, “aim” or “continue”, or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech’s control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech’s estimates of expenses and profitability; (6) Alvotech’s ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech’s partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) Alvotech’s ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (13) the success of Alvotech’s current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech’s ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech’s ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech’s products and product candidates; (17) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company’s business, financial position, strategy and anticipated milestones; and (18) other risks and uncertainties set forth in the sections entitled “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements” in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.