PRESS RELEASE

# Ascendis Pharma's Initial Dose Escalation Results from the Ongoing Phase 1/2 Trial of TransCon™ IL-2 β/γ Accepted for Online Publication at ASCO 2023

**COPENHAGEN**, Denmark, April 3, 2023 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced that initial dose escalation data from the Company's ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 β/γ alone or in combination with pembrolizumab has been accepted for online publication at ASCO 2023, the annual meeting of the American Society of Clinical Oncology being held June 2-6 in Chicago. TransCon IL-2 β/γ is an investigational novel long-acting prodrug with sustained release of an IL-2Rβ/γ-selective analog (IL-2β/γ) designed to address the drawbacks of interleukin-2 (IL-2) cancer immunotherapy through prolonged activation of IL-2Rβ/γ with low $C_{max}$.

"We look forward to sharing this initial dose escalation data, which will guide our selection of the recommended Phase 2 dose of monotherapy TransCon IL-2 β/γ in this ongoing Phase 1/2 trial," said Stina Singel, Executive Vice President, Head of Clinical Development, Oncology at Ascendis Pharma. "Our goal is to address the known shortcomings of current IL-2 immunotherapy, such as short half-life and high $C_{max}$. We believe that our novel approach to achieving sustained activation and expansion of the cytotoxic immune cell types while avoiding upregulation of immunosuppressive cells could, if successful, lead to a potentially best-in-class cancer immunotherapy product."

The primary objectives of the Phase 1 portion of the ongoing Phase 1/2 IL-Believe Trial are to evaluate the safety and tolerability and to define the maximum tolerated dose and recommended Phase 2 dose of TransCon IL-2 β/γ alone or in combination with pembrolizumab in adults with locally advanced or metastatic solid tumors.

**About TransCon IL-2 β/γ**[1]

Recombinant interleukin-2 (IL-2, aldesleukin) is an approved cancer immunotherapy but may cause severe side effects including cytokine release syndrome (CRS) and vascular leak syndrome (VLS). This is believed to be due to activation of IL-2Rα$^+$ endothelial cells and inflammatory eosinophils as well as high $C_{max}$ due to the short half-life requiring frequent high-dose administrations. Potent activation of immunosuppressive IL-2Rα$^+$ regulatory T cells (Tregs) may also limit IL-2's efficacy. TransCon IL-2 β/γ is a novel long-acting prodrug with sustained release of an IL-2Rβ/γ-selective IL-2 analog designed to address these shortcomings. In pre-clinical studies, TransCon IL-2 β/γ has demonstrated improved pharmacokinetics and profound expansion of cytotoxic immune cells in animal models.

**About Ascendis Pharma A/S**

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated, global biopharmaceutical company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company uses its TransCon technologies to create

new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg, Munich, and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit ascendispharma.com to learn more.

**Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Ascendis' future operations, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to (i) Ascendis' ability to address the known shortcomings of current IL-2 immunotherapy to create a potentially best-in-class cancer immunotherapy product (ii) Ascendis' ability to apply its platform technology to build a leading, fully integrated global biopharmaceutical company, and (iii) Ascendis' use of its TransCon technologies to create new and potentially best-in-class therapies. Ascendis may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Ascendis makes, including the following: dependence on third party manufacturers, distributors, and service providers for Ascendis products and product candidates; unforeseen safety or efficacy results in its development programs or on-market products; unforeseen expenses related to commercialization of any approved Ascendis products; expenses related to Ascendis' of its development programs; unforeseen selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the development of its development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; Ascendis' ability to obtain additional funding, if needed, to support its business activities; the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on its business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia. 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 Ascendis' business in general, see Ascendis' Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 2, 2022 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that Ascendis may enter into or make. Ascendis does not assume any obligation to update any forward-looking statements, except as required by law.



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[1] Journal of Clinical Oncology DOI: 10.1200/JCO.2022.40.16_suppl.2563 *Journal of Clinical Oncology* 40, no. 16_suppl (June 01, 2022) 2563-2563.