

# **PRESS RELEASE**

## Ascendis Presents Updated and New TransCon<sup>™</sup> IL-2 β/γ Monotherapy and Combination Therapy Data Confirming Clinical Activity Across Tumor Types at ESMO 2023

- Clinical responses with TransCon IL-2 β/γ demonstrated as monotherapy or in combination with checkpoint inhibitor, including in two of three small cell lung cancer patients treated with combination therapy
- TransCon IL-2  $\beta/\gamma$  administered every three weeks was generally well tolerated as a monotherapy or in combination with pembrolizumab, with no meaningful effect on T<sub>regs</sub> and eosinophils
  - Enrollment continues in indication-specific cohorts for Phase 2 portion of the IL-Believe Trial

**COPENHAGEN, Denmark, October 26, 2023 (GLOBE NEWSWIRE)** – Ascendis Pharma A/S (Nasdaq: ASND) reported updated and new data from its ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2  $\beta/\gamma$  in a poster presentation at ESMO 2023, the annual meeting of the European Society of Medical Oncology held in Madrid, Spain. The data included longer-term follow up of previously presented TransCon IL-2  $\beta/\gamma$  monotherapy data from the IL-Believe Trial, and was the first presentation of dose escalation data informing recommended Phase 2 dose (RP2D) for TransCon IL-2  $\beta/\gamma$  in combination with a checkpoint inhibitor.

As of the August 15, 2023 data cutoff, 46 patients were enrolled into dose escalation: 25 to monotherapy and 21 to combination therapy. Patients were heavily pretreated including some who previously progressed on checkpoint inhibitors. Anti-tumor clinical responses were observed with TransCon IL-2  $\beta/\gamma$ both as monotherapy (colorectal cancer with confirmed partial response (PR)) and in combination with pembrolizumab (small cell lung cancer (SCLC), 1 with confirmed PR and, subsequent to the August 15, 2023 data cutoff, 1 ongoing with an unconfirmed complete response).

"These updated data reinforce the promising Phase 1 monotherapy data for TransCon IL-2  $\beta/\gamma$  reported earlier this year, further strengthening our confidence in its best-in-class potential," said Stina Singel, M.D., Ph.D., Executive Vice President, Head of Clinical Development, Oncology at Ascendis Pharma. "In addition to previously reported monotherapy clinical activity, we are particularly encouraged to see anti-tumor responses in two of the three patients with SCLC in the combination portion of the trial who had previously progressed on checkpoint inhibitors. In the Phase 2 portion of IL-Believe, we continue enrolling into indication-specific cohorts and look forward to sharing preliminary data from these cohorts in the second half of 2024."

TransCon IL-2  $\beta/\gamma$  is an investigational long-acting prodrug with sustained release of an IL-2R $\beta/\gamma$ -selective analog (IL-2  $\beta/\gamma$ ) designed to address the known limitations of interleukin-2 (IL-2) cancer



immunotherapy through prolonged activation of IL-2R $\beta/\gamma$  with low C<sub>max</sub>. IL-Believe is investigating the safety and tolerability of TransCon IL-2  $\beta/\gamma$  alone or in combination with the check-point inhibitor pembrolizumab and/or chemotherapy or TransCon TLR7/8 Agonist in participants with locally advanced or metastatic solid tumors. RP2D for IL-Believe is 120 µg/kg of TransCon IL-2  $\beta/\gamma$  administered intravenously every three weeks in both the monotherapy and combination therapy arms.

Additional details and highlights from the ESMO poster are available on the Investor & News section of the Ascendis Pharma website at https://investors.ascendispharma.com.

### About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated biopharma 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 Germany (Heidelberg and Munich) and the United States (Palo Alto and Redwood City, California, and Princeton, New Jersey). Please visit <u>ascendispharma.com</u> 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' belief of the best-in-class potential of TransCon IL-2  $\beta/\gamma$ ; (ii) the timing of data from indication-specific cohorts for TransCon IL-2  $\beta/\gamma$ ; (iii) the ability of TransCon IL-2  $\beta/\gamma$  to address the known limitations of interleukin-2 (IL-2) cancer immunotherapy through prolonged activation of IL-2R $\beta/\gamma$ ; (iv) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated, global biopharma company; and (v) 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 onmarket products; unforeseen expenses related to commercialization of any approved Ascendis products; unforeseen expenses related to Ascendis' development programs; unforeseen selling, general and administrative expenses; other research and development expenses and Ascendis' business generally; delays in the development of its 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 ongoing conflicts such as that 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 February 16, 2023 and Ascendis' other future reports filed with, or submitted to, the SEC. Forwardlooking 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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