PRESS RELEASE

Ascendis to Present First Results from Platinum-Resistant Ovarian Cancer (PROC) Cohort of the Phase 1/2 IL-Believe Trial at ESMO 2024

- *Anti-tumor clinical responses were observed in 29% (4/14) of efficacy-evaluable patients with PROC treated with TransCon IL-2 β/γ in combination with chemotherapy*
- *Initial data suggest clinical activity in heavily pre-treated PROC patients and that TransCon IL-2 β/γ in combination with chemotherapy was generally well-tolerated*

COPENHAGEN, Denmark, September 13, 2024 (GLOBE NEWSWIRE) – Ascendis Pharma A/S (Nasdaq: ASND) today announced initial data showing signs of clinical activity in heavily pre-treated patients with platinum-resistant ovarian cancer (PROC) treated with TransCon IL-2 β/γ in combination with chemotherapy in its ongoing Phase 1/2 IL-Believe Trial of TransCon IL-2 β/γ. First results will be shared in Poster 762P at ESMO 2024, the annual meeting of the European Society of Medical Oncology being held in Barcelona from September 13-17, 2024.

Of the 18 patients (median age 64 years) included in the initial data, 14 were efficacy evaluable patients who had 1 or more post-baseline tumor assessment(s), plus an additional 4 who discontinued treatment before the first post-baseline tumor assessment due to disease progression or death. Anti-tumor clinical responses were observed in 29% (4/14) of the efficacy evaluable patients (2 confirmed and 2 unconfirmed partial responses in patients who had received three to seven prior lines of treatment – including patients whose disease had previously progressed on Elahere®, also called mirvetuximab soravtansine-gynx), suggesting clinical activity in heavily pre-treated patients. The data suggest that TransCon IL-2 β/γ was generally well-tolerated: the most common treatment-emergent adverse events related to combination therapy with TransCon IL-2 β/γ plus chemotherapy were fatigue, thrombocytopenia, neutropenia, and anemia. Most TransCon IL-2 β/γ-related TEAEs were grade 1 or 2.

“Building on results announced at ASCO 2024 in melanoma, we are excited now to see meaningful signs of anti-tumor activity in combination with chemotherapy in our second indication-specific cohort of heavily pretreated patients who have exhausted standard-of-care options,” said Stina Singel, M.D., Ph.D., Executive Vice President, Head of Clinical Development, Oncology, at Ascendis Pharma. “We look forward to providing further updates as patients continue on study treatment.”

About TransCon IL-2 β/γ & IL-Believe

TransCon IL-2 β/γ is a novel prodrug with sustained release of an IL-2Rβ/γ-selective IL-2 analogue (IL-2 β/γ). IL-2 β/γ is transiently attached to an inert carrier by a TransCon linker, which under physiological conditions releases active IL-2 β/γ in a predictable, sustained manner. This results in lower C_{max} and longer half-life, which is expected to widen the therapeutic index.

TransCon IL-2 b/g is being investigated in IL Believe, a multicenter Phase 1/2, multi-cohort study in adult patients with locally advanced or metastatic solid tumors. As of the July 29, 2024, data cut off, 42 patients whose disease had progressed within six months after completing platinum-based chemotherapy were enrolled in the PROC dose expansion cohort (Cohort 3 in the trial). Treatment for patients in Cohort 3 included intravenous TransCon IL-2 β/γ at the recommended Phase 2 dose of 120 µg/kg every 3 weeks in combination with the physician's choice of paclitaxel, docetaxel, or pemetrexed. Disease response was assessed every 9 weeks using RECIST v1.1. and safety, efficacy, and biomarkers were evaluated.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative TransCon technology platform 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, Ascendis uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark and has additional facilities in Europe and the United States. 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' intent to provide further updates as patients continue on treatment with TransCon IL-2 β/γ in combination with chemotherapy, (ii) Ascendis' ability to apply its TransCon technology platform to build a leading, fully integrated biopharma 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 Ascendis' development programs or on-market 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. 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 7, 2024, 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.

Ascendis, Ascendis Pharma, the Ascendis Pharma logo, the company logo, and TransCon are trademarks owned by the Ascendis Pharma group. Elahere® is a registered trademark of ImmunoGen, Inc.

Investor Contacts:
Tim Lee
Ascendis Pharma
+1 (650) 374-6343
tle@ascendispharma.com
ir@ascendispharma.com

Patti Bank
ICR Westwicke
+1 (415) 513-1284
patti.bank@westwicke.com

Media Contact:
Melinda Baker
Ascendis Pharma
+1 (650) 709-8875
media@ascendispharma.com