Amicus Therapeutics Reports Preliminary 2024 Revenue and Provides 2025 Strategic Outlook

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2024 Total Revenue of $528M, Representing Significant Growth of 32% Year-Over-Year[1]

Strong and Growing Demand for Galafold® and Pombiliti® + Opfolda®

Total Revenue Growth of 17-24% at CER Expected in 2025

>3,000 People Treated with an Amicus Therapy Today[2]

PRINCETON, N.J., Jan. 12, 2025 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today provided its preliminary and unaudited 2024 revenue, corporate updates, and full-year 2025 outlook.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., said, “For Amicus, 2024 was a remarkable year in which we set out high expectations and met or exceeded each of them. Amicus delivered significant revenue growth of 32% in addition to Full Year non-GAAP profitability. We grew our core Galafold business and delivered a strong first full year of launch for Pombiliti + Opfolda while securing regulatory and reimbursement milestones that provide the foundation for sustained double-digit growth in 2025 and beyond. The combination of two approved medicines in growing markets, our strong intellectual property position, accelerating profitability, and our unique and leverageable global rare disease organization will enable us to deliver sustainable revenue growth and expand our portfolio over time. We have the capabilities and infrastructure to achieve our vision to become one of the leading rare disease companies bringing transformative therapies to patients and creating significant value for shareholders.”

Corporate Highlights:

- **Total revenue in 2024 reached $528.5 million** (preliminary and unaudited), representing a year-over-year increase of 32%, reflecting strong operational growth of 32% at constant exchange rates (CER)[3]. Fourth quarter total revenue was $149.9 million. For the full year 2025, the Company anticipates total revenue growth of 17-24% on a constant currency basis[3].
- **Galafold (migalastat) net product sales in 2024 were $458.2 million** (preliminary and unaudited)**,** representing a year-over-year increase of 18%, or 18% at CER[3]. Fourth quarter Galafold net product sales were $127.7 million. Given significant growth in patient demand and continued market leadership, there were ~2,730 patients living with Fabry disease on Galafold as of the end of 2024. For the full year 2025, the Company anticipates Galafold revenue growth of 10-15% on a constant currency basis[3].
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales in 2024 were $70.3 million** (preliminary and unaudited)**.** Fourth quarter Pombiliti + Opfolda net product sales were $22.2 million. Following a successful first full year of commercial launch, there were ~220 patients treated or scheduled with commercial product as of the end of 2024. For the full year 2025, the Company anticipates Pombiliti + Opfolda revenue growth of 65-85% on a constant currency basis[3].
- **Multiple Pombiliti + Opfolda pricing and reimbursement agreements recently achieved**. Agreements completed in late 2024 and early 2025 include Italy, Sweden, Switzerland, and Czech Republic. First commercial patients from these countries are anticipated to begin treatment over the first half of 2025. The Company also anticipates new regulatory decisions in Australia, Canada, and Japan in 2025 as well as additional reimbursement agreements throughout the year.
- **As previously announced, Amicus reached a settlement with Teva on the Galafold U.S. patent litigation.** Based on the settlement terms, Teva will not be able to commercialize generic migalastat in the U.S. until Jan 2037.
- **Amicus is focused on delivering significant long-term revenue growth and anticipates surpassing $1 billion in total sales in 2028.** The Company anticipates continuing to grow its current commercial business with Galafold and Pombiliti + Opfolda resulting in strong revenue growth. Based on current operating plans, Amicus anticipates achieving **positive GAAP Net Income** during H2 2025.

Amicus is focused on the following key strategic priorities in 2025:

- Delivering total revenue growth of 17-24% at CER[3]
- Galafold revenue growth of 10-15% at CER[3]

- Pombiliti + Opfolda revenue growth of 65-85% at CER[3]
- Advancing ongoing studies to broaden labels and scientific leadership in Fabry and Pompe diseases
- Delivering positive GAAP Net Income during H2 2025

Mr. Campbell will discuss the Amicus corporate objectives and key milestones in a presentation at the 43rd Annual J.P. Morgan Healthcare Conference on Monday, January 13, 2025, at 3:00 p.m. PT. A live webcast of the presentation can be accessed through the Investors section of the Amicus Therapeutics corporate website at http://ir.amicusrx.com/events.cfm, and will be archived for 90 days.

[1] Preliminary and unaudited

[2] Including clinical trial and expand access participants

[3] At constant exchange rates (CER). In order to illustrate underlying performance, Amicus discusses its results in terms of CER growth. This represents growth calculated as if the exchange rates had remained unchanged from those used in the comparative period.

About Galafold

Galafold® (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable galactosidase alpha gene *(GLA)* variants. In these patients, Galafold works by stabilizing the body's own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of people living with Fabry disease may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in more than 40 countries around the world, including the U.S., EU, U.K., and Japan.

U.S. INDICATIONS AND USAGE

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

USE IN SPECIFIC POPULATIONS

There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf.

About Pombiliti + Opfolda

Pombiliti + Opfolda, is a two-component therapy that consists of cipaglucosidase alfa-atga, a bis-M6P-enriched rhGAA that facilitates high-affinity uptake through the M6P receptor while retaining its capacity for processing into the most active form of the enzyme, and the oral enzyme stabilizer, miglustat, that's designed to reduce loss of enzyme activity in the blood.

U.S. INDICATIONS AND USAGE

POMBILITI in combination with OPFOLDA is indicated for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS: Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, POMBILITI should be discontinued immediately and appropriate medical treatment should be initiated. INFUSION-ASSOCIATED REACTIONS (IARs): If severe IARs occur, immediately discontinue POMBILITI and initiate appropriate medical treatment. RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS: Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion. See PI for complete Boxed Warning. CONTRAINDICATION: POMBILITI in combination with Opfolda is contraindicated in pregnancy. **EMBRYO-FETAL TOXICITY:** May cause embryo-fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least 60 days after the last dose. **Adverse Reactions:** Most common adverse reactions ≥ 5% are headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia. **Please see full PRESCRIBING INFORMATION, including BOXED WARNING, for POMBILITI (cipaglucosidase alfa-atga) LINK and full PRESCRIBING INFORMATION for OPFOLDA (miglustat) LINK.**

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information, please visit the Company's website at

www.amicusrx.com, and follow on X and LinkedIn.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We use these non-GAAP measures as key performance measures for the purpose of evaluating operational performance and cash requirements internally. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. When we provide our expectation for non-GAAP operating expenses and profitability on a forward-looking basis, a reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variability, complexity and low visibility as to the items that would be excluded from the GAAP measure in the relevant future period, such as unusual gains or losses. The variability of the excluded items may have a significant, and potentially unpredictable, impact on our future GAAP results.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the prospects and timing of the potential regulatory and pricing and reimbursement approvals of our products, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues, profitability and cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities and pricing and reimbursement authorities, are based on current information. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that required regulatory inspections may be delayed or not be successful and delay or prevent product approval; the potential that we may not be successful in negotiations with pricing and reimbursement authorities; the potential that we may not be successful in commercializing Galafold and/or Pombiliti and Opfolda in Europe, the UK, the US and other geographies; the potential that we will not be able to effectively compete in our approved markets: the potential that generic or new competitor products enter the market; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to support the manufacturing and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue, non-GAAP and GAAP profitability and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2023, and on Form 10-Q for the quarter ended September 30, 2024. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

CONTACT:

Investors:
Amicus Therapeutics
Andrew Faughnan
Vice President, Investor Relations
afaughnan@amicusrx.com
(609) 662-3809

Media:
Amicus Therapeutics
Diana Moore
Head of Global Corporate Communications
dmoore@amicusrx.com
(609) 662-5079

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