



Amicus Therapeutics Announces Preliminary Third Quarter 2019 Revenue and Financial Outlook at 2019 Analyst Day

October 10, 2019

Analyst Day 2019 to Highlight Financial Outlook and Robust Portfolio of Novel Therapies for Rare Metabolic Diseases

3Q19 Galafold® (migalastat) Preliminary Unaudited Revenue of ~\$48M+ and 1,000+ Patients on Therapy Reflects Continued Strong Global Uptake

Company Raises Lower End of FY19 Global Galafold Revenue Guidance to \$170M-\$180M on Significant Momentum Across All Major Geographies

Cash Runway Extended from 2021 to Well Into 1H 2022

Analyst Day 2019 Webcast to begin at 8:30a.m. ET

CRANBURY, N.J., Oct. 10, 2019 (GLOBE NEWSWIRE) -- [Amicus Therapeutics](http://www.amicusrx.com) (Nasdaq: FOLD) today announced preliminary unaudited revenue for the third quarter of 2019 in advance of its Analyst Day, to be held today, October 10, 2019, in New York City at 8:30 a.m. Today's Analyst Day will highlight the financial strength and outlook of the Company in addition to recent progress and updates related to its early- and late-stage rare disease portfolio, including a late-stage biologic AT-GAA with breakthrough therapy designation (BTD) for Pompe disease, a clinical-stage intrathecal AAV gene therapy with positive interim results in CLN6 Batten disease, and a robust gene therapy pipeline.

The live event will be audio webcasted simultaneously and accessible via the Investors section of the Amicus Therapeutics corporate website at <http://ir.amicusrx.com/events-and-presentations>, and will be archived for 90 days.

Preliminary Third Quarter 2019 Revenue

Amicus expects to record approximately \$48 million (preliminary and unaudited) in Galafold revenue for the third quarter 2019, a year-over-year increase of over 133% from total revenue of \$20.6 million in the third quarter of 2018, and a quarter over-quarter increase of over 8.8% from total revenue of \$44.1 million in the second quarter of 2019. The Company also achieved its goal of 1,000 patients treated with Galafold during the third quarter. Global compliance and adherence rates continue to exceed 90%.

Revenue Guidance and Financial Outlook

Following the success in the first three quarters of the year, in addition to the strength in global Galafold launch metrics across all major geographies, Amicus is now raising the lower end of the full-year 2019 Galafold revenue guidance from \$160 to \$180 million to \$170 to \$180 million. Following a diligent review of current and outer year operating and capital expense projections, and robust outlook for Galafold revenue, Amicus now expects to end 2019 with more than \$420 million in cash on hand and has extended the cash runway projection from 2021 to well into the first half of 2022.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc. stated, "We are very pleased to host our Amicus Analyst Day this morning on the heels of such significant momentum across our entire portfolio. With a global commercial medicine, our late-stage Pompe biologic, and one of the industry's largest gene therapy pipelines, we are also fully funded to achieve our major upcoming milestones as we continue to build a leading global biotechnology company. With the strength of our third quarter financials and overall financial outlook, we are well capitalized and optimally positioned to achieve growing revenues that significantly contribute to our pipeline investments and advance us toward profitability."

Amicus Analyst Day 2019 Key Takeaways

1. Galafold continues strong launch performance and cornerstone of Amicus success with 1,000+ net global Galafold patients treated and clear path to projected \$500M+ in 2023 and \$1B+ peak revenue
2. Financial outlook strengthened with current cash now revised to well into 1H 2022 through major portfolio milestones and global growth
3. AT-GAA for Pompe advances toward approval as "crown jewel" of Amicus portfolio with peak revenue potential of \$1B-\$2B, with exclusivity well into 2030s
4. Portfolio of gene therapy programs and technologies provides foundation for future, including two clinical-stage programs

(CLN6 and CLN3), a Pompe gene therapy clinical candidate declared to move into IND-enabling studies, and eight additional preclinical gene therapies

Amicus Analyst Day Agenda:

Today's Amicus Analyst Day agenda is expected to run from 8:30am ET to Noon ET to highlight the Company's overall vision and strategy as well as recent progress and new updates across the entire portfolio.

- **Vision, Mission and Strategy**
- **Financial and Operational Strategy**
- **GalaFold: Roadmap to \$1B in Sales and Patient Perspectives**
- **AT-GAA: Potential to Shift the Treatment Paradigm in Pompe Disease**
- **Next Generational Gene Therapy Platform & Research Program**
- **Batten Disease Gene Therapy Portfolio and Patient Perspectives**

The Amicus team will be joined by several external guests including James M. Wilson, M.D., Ph.D., Professor of Medicine and Pediatrics, Perelman School of Medicine; Sabina Kineen and Alex Dencker, two individuals living with Fabry disease; and David and Karen Kahn, parents and caregivers to two daughters, Amelia and Makenzie, living with CLN3 Batten disease.

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 metabolic diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at www.amicusrx.com, and follow on [Twitter](#) and [LinkedIn](#).

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing and supply plans, financing plans, business development plans and the projected revenues, sales, expenses 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 or projections 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, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, 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 results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing GalaFold in Europe, Japan, the US and other geographies or our other product candidates if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; 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 complete all of our studies and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With respect to statements regarding projections of the Company's revenue, sales, expenses and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans and strategies. 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, 2018. 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 press release to reflect events or circumstances after the date hereof.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation 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 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 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.

CONTACTS:

Investors:

Amicus Therapeutics
Sara Pellegrino, IRC
Vice President, Investor Relations
spellegrino@amicusrx.com
(609) 662-5044

Media:

Christopher Byrne
Executive Director, Corporate Communications
cbyrne@amicusrx.com
609-662-2798

FOLD-G



Source: Amicus Therapeutics, Inc.