

CEO's corner

Michael Castagna, PharmD
Chief Executive Officer

“ Our year began with strengthening the company’s financial position, and we are energized by the path ahead as we continue to advance our pipeline, support the regulatory review of Tyvaso DPI™ and grow Afrezza®. MannKind is driven to deliver therapeutics in ways that can help improve patient lives, while our Technosphere® technology continues to be a conduit of future potential. ”

company news



TYVASO DPI

MannKind and United Therapeutics Corporation reached a major milestone in June with the announcement that the U.S. Food and Drug Administration (FDA) accepted for priority review the New Drug Application (NDA) for Tyvaso DPI (inhaled treprostinil) for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). Agency review is expected to be complete in October 2021. A hiring expansion is underway at MannKind’s manufacturing facility in Danbury, Conn., as we prepare to transition from producing clinical supply to building pre-launch inventory of Tyvaso DPI, pending FDA approval.



PIPELINE

MannKind and Thirona Bio announced that they have joined forces to advance the development of novel compound FBMS712 with potential for multiple indications. Under the terms of the collaboration agreement, the companies will evaluate the therapeutic potential of Thirona’s locally acting TGF- inhibitor for the treatment of pulmonary fibrosis. MannKind will formulate FBMS712 as a dry powder formulation. If initial studies are promising, MannKind can exercise certain rights to seek a full license to the compound for clinical development and commercialization for the treatment of fibrotic pulmonary diseases.

Nebulized clofazimine (MNKD-101) for nontuberculous mycobacterial lung infection is expected to be ready for Phase 1 submission by year-end 2021. In preclinical studies, clofazimine has demonstrated optimal antibiotic (MIC) characteristics and a strong reduction in bacterial recovery vs. saline control (4 log; 99.99% reduction).



AFREZZA

Site initiation activities are being planned for the INHALE-1 Study, a 26-week open-label, randomized clinical trial (with a 26-week extension) evaluating the efficacy and safety of Afrezza with basal insulin vs multiple daily injections of insulin in pediatric patients (aged 4-17) living with type 1 diabetes (T1D) or type 2 diabetes (T2D).

in the news

Medicare policy change impacts Afrezza in the positive

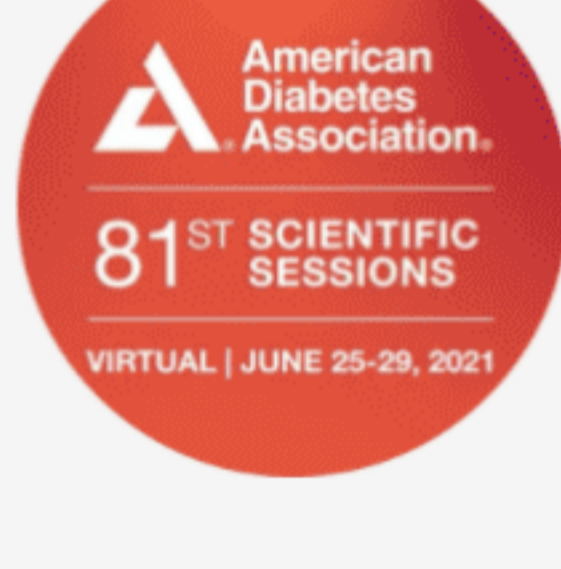


MannKind Corporation appreciates the recent efforts of the Centers for Medicare and Medicaid Services (CMS) in conjunction with the Medicare Administration Contractors (MACs) to implement a policy change to the Local Coverage Determination (LCD) L33822, allowing Medicare patients living with diabetes to select both Afrezza and Continuous Glucose Monitors (CGMs). Effective July 18, 2021, the criteria change lifts the restriction on patients of having to choose between the two diabetes tools. This is a win-win situation for Medicare patients and providers that serve those patients.

[read more →](#)

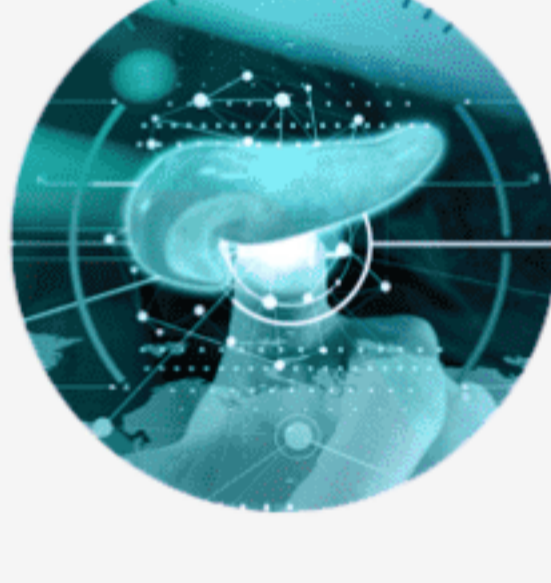
MannKind presented two posters at ADA’s 81st Scientific Sessions

The American Diabetes Association’s virtual 81st Scientific Sessions were held June 25-29, and MannKind presented two posters – one reporting Phase 2 clinical study results of Afrezza in pediatric subjects, and a second presenting a retrospective analysis of the effect of prandial inhaled insulin on daytime glucose levels in people with uncontrolled type 2 diabetes. The results, respectively, showed (1) that Afrezza has similar pharmacokinetics in pediatric patients as in adults, and (2) that inhaled insulin increases daytime time-in-range and decreases daytime hyperglycemia.



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Study demonstrates Afrezza reduced nocturnal hypoglycemia

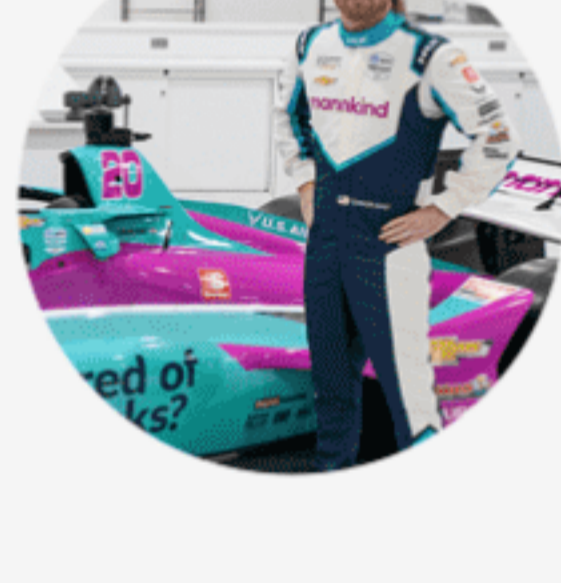


MannKind presented data June 2-5 at the 14th International Conference on Advanced Technologies & Treatments for Diabetes (ATT2021) from a post-hoc analysis of the STAT study. The poster presented how Technosphere Insulin reduced nocturnal hypoglycemia compared to insulin aspartate in adult patients with T1D.

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Tired of Pricks? T1D IndyCar driver raises awareness

MannKind recently announced a partnership with IndyCar driver Conor Daly to help raise awareness about diabetes and innovative management options. As part of the connectivity, MannKind also was a primary sponsor for Ed Carpenter Racing as Daly debuted the No. 20 MannKind Chevrolet at the May 15th running of the GMR Grand Prix at Indianapolis Motor Speedway. Daly’s bold and bright livery featured an edgy “Tired of Pricks?” tagline – a purposeful wordplay designed to draw attention to NeedleFreeInsulin.com. First diagnosed with diabetes at the age of 14, Daly is the only known U.S. professional racing driver who competes full-time while living with type 1 diabetes.



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financial & stock performance



\$278M

Cash, cash equivalents, and investments
(as of March 31, 2021)

\$17M

Total revenue for 1Q of 2021

7% ^

Increase in total revenue
(in comparison to 1Q 2020)

[See 2021 1Q Financial Results →](#)

stock performance *

Equity/Index	Price: 12/31/19	Price: 12/31/20	Price: 6/30/21
MNKD	\$1.29	\$3.13	\$5.45

Equity/Index	Price: 12/31/19	Price: 12/31/20	Price: 6/30/21
R3000 P&B Index	\$3,052.93	\$3,459.41	\$3,740.20

Equity/Index	% Change - 3 Yrs 7/1/18 - 6/30/21	% Change - 1 Yr 7/1/20 - 6/30/21	% Change - 6 Mos 1/1/21 - 6/30/21
MNKD	+186.8%	+222.5%	+74.1%

Equity/Index	% Change - 3 Yrs 7/1/18 - 6/30/21	% Change - 1 Yr 7/1/20 - 6/30/21	% Change - 6 Mos 1/1/21 - 6/30/21
R3000 P&B Index	+43.5%	+18.3%	+8.1%

* Stock price return over the course of 2020 for both MannKind and the Russell 3000 Pharmaceuticals & Biotech index provided via Bloomberg.

events

August 9 **BTIG Virtual Biotechnology Conference →**

August 12-15 **Association of Diabetes Care & Education Specialists Conference →**

1H August **MannKind 2Q 2021 Earnings Call**

connect with us.

Reach out anytime. We'd love to hear from you.

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