



Airway Therapeutics and Celonic Group Collaborate to Produce AT-100 as Promising New Candidate for Coronavirus

AT-100 production expected to begin in June

CINCINNATI, OH & BASEL, Switzerland (May 20, 2020) – Airway Therapeutics, Inc., a biopharmaceutical company developing a new class of biologics to break the cycle of injury and inflammation for patients with respiratory and inflammatory diseases, and Celonic Group, a premium biopharmaceutical CDMO specialized in the development and production of Advance Therapy Medicinal Products (ATMPs) and mammalian cell line-expressed biotherapeutics, today announced a collaboration to produce the novel human recombinant protein AT-100 (rhSP-D) as a therapeutic candidate against COVID-19. Based on the agreement, Celonic will be responsible for process optimization and GMP manufacturing of AT-100 for clinical study. Production of AT-100 is expected to begin in June 2020.

"AT-100 has shown great potential in addressing the inflammation and injury caused by serious respiratory diseases driven by infection but has never been produced for larger-scale clinical trial indications," said Marc Salzberg, M.D., President and Chief Executive Officer of Airway. "Airway has dedicated significant time and resources to develop a manufacturing process for AT-100 – leading the path to clinical development. Given the urgency of the current pandemic, I am thrilled to establish this collaboration with Celonic, a leader in biologic manufacturing, to increase the scale of our production capabilities with the potential to meet the needs of patients."

"At Celonic, we are excited and proud to work with Airway and join the fight against this worldwide pandemic," said Konstantin Matentzoglu, Ph.D., Chief Executive Officer of Celonic. "AT-100 has the potential to be a lifesaving treatment for COVID-19 patients until a vaccine is available, especially for those who are very seriously ill and in intensive care.

Together, we have an opportunity to make a difference in the lives of patients at this time of great need."

AT-100 is an engineered version of an endogenous protein that has been shown in preclinical studies to reduce inflammation and infection in a range of bacterial and viral respiratory diseases by modulating the body's immune response. Airway has previously filed a pre-IND submission with the U.S. Food and Drug Administration (FDA) for AT-100 as a preventive treatment of the serious respiratory disease bronchopulmonary dysplasia (BPD) in very preterm infants, with an IND filing expected in Q3 and plans to enter the clinic in late 2020.

"I am proud of the combined team who worked tirelessly over several months to transfer the AT-100 manufacturing technology to Celonic in order to produce a scaled, GMP batch for clinical study in COVID-19 patients," said Alan Wolk, Chief Financial and Operating Officer of Airway. "Airway is inspired, engaged and enthusiastic to contribute in the effort to overcoming the pandemic through the therapeutic potential of AT-100."

Celonic's human cell line expression system, with fully human glycosylation, is an excellent platform for high-yield GMP production of difficult-to-express complex molecules such as bispecific antibodies, fusion proteins, antibody fragment and blood factors. Celonic is one of the unique global bio-solutions providers that can offer perfusion continuous cell culture manufacturing – for both CHO and human cell lines – at a large 1,000-liter bioreactor scale.

"The global battle against COVID-19 requires urgent and concerted efforts," said Vikalp Mohan, Chief Operating Officer of Celonic. "Swift strategic alignment and operational flexibility have been the hallmark of a highly collaborative partnership between Airway and Celonic. We are honored to have this opportunity to leverage our advanced perfusion cell culture manufacturing expertise to help realize the therapeutic potential of AT-100."

About AT-100

AT-100 is a novel recombinant human protein rhSP-D, an engineered version of an endogenous protein that reduces inflammation and infection in the body while modulating the immune response to break the cycle of injury and inflammation. Airway is focused on advancing AT-100 as a potential therapeutic for very serious COVID-19 patients and for the prevention of bronchopulmonary dysplasia (BPD) in very preterm infants. AT-100's anti-

inflammatory and anti-infective properties also make it a potential treatment for other

respiratory diseases such as influenza, respiratory syncytial virus (RSV) and inflammatory

diseases inside and outside the lung. Airway has filed a pre-IND submission with the FDA for

AT-100 as a preventative treatment for BPD.

About Airway Therapeutics

Airway Therapeutics, based in Cincinnati, OH, is a biopharmaceutical company developing a

new class of biologics to break the cycle of injury and inflammation for patients with

respiratory and inflammatory diseases, beginning with the most vulnerable populations. The

company is advancing the novel recombinant human protein rhSP-D, an engineered version of

an endogenous protein that reduces inflammation and infection in the body while modulating

the immune response. AT-100 is Airway's first candidate in development for the prevention

of bronchopulmonary dysplasia (BPD) in very preterm infants. To learn more, visit

https://www.airwaytherapeutics.com.

About Celonic

Celonic Group is a privately-owned CDMO based in Basel, Switzerland, with a state-of-the-

art bio manufacturing facility in Heidelberg, Germany. Celonic provides comprehensive

development and manufacturing services for bio therapeutics including cell line development,

USP and DSP development, GMP and non-GMP manufacturing of biopharmaceutical drug

substances and drug products, along with cell expression platforms and diagnostics. Celonic

offers two cell expression platforms to clients, developers, and service providers –

CHOvolution®, developed by Celonic and GEX®, developed by Glycotope GmbH and in-

license by Celonic. With a new GMP manufacturing facility for gene vectors and cell therapy,

Celonic is soon expanding its services to the manufacturing of gene vectors and allogenic cell

batches. For more information, visit www.celonic.com.

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