



Catalent Pharma Solutions
14 Schoolhouse Road
Somerset NJ 08873 USA
T (732) 537 6200
F (732) 537 6480
www.catalent.com



Press Release

Media Contacts:

Chris Halling
+44 (0)7580 041073
chris.halling@catalent.com

Richard Kerns
+44 (0) 161 728 5880
richard@nepr.eu

Andreas Herrmann
+41 (0) 61 2053 910
andreas.herrmann@valeriusbio.com

Catalent Biologics and Valerius Biopharma to Collaborate on Manufacture of Specialty Biosimilars

Somerset, N.J. and Basel, Switzerland – May 14, 2018 — Catalent Pharma Solutions, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, and Valerius Biopharma AG, a Swiss biopharmaceutical company dedicated to providing interchangeable treatment options for high-priced orphan and non-orphan biologics, today announced that they are to collaborate on the development and manufacture of Valerius' biosimilar products.

Under the agreement, Catalent Biologics will provide cell line development and support cGMP manufacturing activities from Phase I through to commercial stages at its state-of-the-art biologics manufacturing facility in Madison, Wisconsin.

The project will utilize Catalent's proprietary GPEX[®] technology, which creates high-performance, highly stable production cell lines in a wide variety of mammalian host cells. To date, over 460 different mAb and mAb fusions, and over 50 different recombinant proteins have been produced using the GPEX system achieving large scale fed-batch production titers of over 7 g/L. The advantages of applying GPEX technology span from early feasibility studies, to clinical manufacturing, to commercial scale production.

Valerius Biopharma AG is a biopharmaceutical company founded to develop biosimilar products as alternatives to high-priced biologics, for indications where there is a substantial medical need. The company has built a research and development hub of scientists and experts with decades of

experience in the development of biopharmaceutical and biosimilar compounds, as well as profound clinical and regulatory expertise. The company's current product pipeline comprises four biosimilar products in different development stages.

"Our business mission is to make the treatment of severe, life-threatening and rare diseases more affordable for patients worldwide by developing biosimilars that meet the highest regulatory standards," commented Andreas Herrmann, CEO of Valerius. He added, *"We selected Catalent as our development and manufacturing partner because of their technical knowledge and expertise in the cGMP manufacture of biosimilars, and proven track record in bringing innovative treatments to market."*

Mike Riley, Vice President and General Manager of Drug Substance and Bioanalytical Services, Catalent Biologics, added, *"We are pleased to partner with Valerius on their biologic-based therapeutics for many important indications. We look forward to supporting them in their goal of producing affordable biosimilars that will provide more equal access to medicinal products."*

Opened in April 2013 and recently expanded, Catalent Biologics' Madison site provides development, manufacturing and analytical services for new biological entities and biosimilars. The facility was designed for flexible cGMP production from 10 liter up to 4,000 liter scale, and non-GMP production up to 250 liter scale and makes extensive use of single-use technologies and unidirectional flow to maximize safety and efficiency. Manufacturing is supported by integrated analytical, process and formulation development capabilities and separate microbiology and quality control functions.

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About Valerius

Valerius Biopharma AG is a Swiss biopharmaceutical company that has been founded to provide interchangeable treatment options for high-priced biologics, by developing specialty biosimilars for therapeutic indications with high medical need. The current product pipeline consists of two orphan and two non-orphan biosimilar drugs being developed according to highest regulatory standards to enable global access.



Valerius is committed to make the treatment of severe, life-threatening, and rare diseases more affordable for all patients worldwide. For further information, please visit www.valeriusbio.com.

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 11,000 people, including over 1,400 scientists, at more than 30 facilities across five continents, and in fiscal 2017 generated over \$2 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

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