

**Calypso Biotech announces first patient with Eosinophilic Esophagitis dosed in anti-Interleukin-15 (IL-15) monoclonal antibody CALY-002 Phase 1a/b Trial, and animal proof of concept data in Atopic Dermatitis.**

- Healthy volunteers phase completed showing differentiating target engagement biomarker data and favorable safety data
- On track for top-line histology data in 2023 in Celiac Disease and Eosinophilic Esophagitis
- Proof-of-concept data of CALY-002 in humanized Atopic Dermatitis model supports “pipeline-in-a drug” value proposition

**Amsterdam, 15 December 2022** | Calypso Biotech, a leader in the development of Interleukin-15 (IL-15) targeted therapies, announces today dosing of the first Eosinophilic Esophagitis patient in the multiple dosing part of the Phase 1 clinical trial of CALY-002, a novel humanized - and highly differentiated - monoclonal antibody neutralizing IL-15. The ongoing Phase 1 clinical study of CALY-002 includes a single ascending dose (SAD) in Healthy Volunteers as well as multiple ascending dosing (MAD) in cohorts of patients with Celiac Disease or Eosinophilic Esophagitis, two indications with significant unmet medical need where IL-15 plays a critical role in their pathogenesis [NCT04593251].

The SAD part of the study has been completed. Across the wide range of tested dose levels in Healthy Volunteers, CALY-002 was well tolerated, with a PK profile typical for IgG monoclonal antibodies. Importantly, target engagement (i.e., IL-15 blockade) was demonstrated through the reduction of NK cell numbers in blood, owing to the well-known role of IL-15 as a homeostatic factor for NK cells. CALY-002 is the first IL-15-specific antibody to demonstrate blood NK cell reduction in humans, underpinning its unique and differentiated profile.

The MAD part of the study in patients with Celiac Disease or Eosinophilic Esophagitis is currently progressing into the highest dose cohorts . This phase investigates safety, PK, pharmacology, disease biomarkers and clinical efficacy endpoints including histology of multiple doses of CALY-002 or placebo over either an 8-week treatment period in a gluten-challenge setting (Celiac Disease) or a 12-week period of open label CALY-002 treatment (Eosinophilic Esophagitis). Top-line histology data will be generated in 2023 for both indications.

Further, CALY-002 was demonstrated to be active in a recently developed humanized model of Atopic Dermatitis, results presented at the 51<sup>st</sup> European Society for Dermatological Research conference (Amsterdam, 28 September – 01 October 2022). These important data further highlight the potential of CALY-002 in multiple auto-immune indications.

Calypso Biotech Chief Medical Officer, Dr. Jos Houbiers, MD, PhD, comments “the demonstrated pharmacological efficacy highlights the potency of CALY-002 and is promising for the clinical histology results in the MAD parts of the study. New and improved treatments



are much needed for Celiac Disease and Eosinophilic Esophagitis patients who have limited treatment options. For patients with celiac disease, clinical practice learns that adherence to a gluten-free diet is very difficult and many patients continue to experience symptoms; in asymptomatic patients, histological damage to the small intestine can be present unnoticed, studies show.”

### **About Calypso Biotech BV**

Calypso Biotech BV is a private biotechnology company focused on the research and development of novel biologics to address unmet medical need in autoimmune and inflammatory diseases, with a unique expertise in IL-15 biology. IL-15 controls immune pathways critically involved in disease onset and maintenance (“disease memory”), as well as tissue destruction, in addition to its broad effect on inflammation. Calypso’s approach offers significant advantages over traditional cytokine interventional therapies and could provide for unprecedented long lasting disease-modifying effects in multiple autoimmune diseases. Calypso Biotech is a spin-off by the healthcare business of Merck KGaA and is headquartered in Amsterdam, The Netherlands, with offices and laboratories in Geneva, Switzerland. For more information see [www.calypsobiotech.com](http://www.calypsobiotech.com)