argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. We are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need.

Expanded access: Expanded access (sometimes called “compassionate use”) is the use of investigational drugs, biologics or medical devices outside the clinical trial setting for treatment purposes. Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrolment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product’s development or marketing approval for the treatment indication.
- The access provisions described above are allowed by local laws and regulations.

argenx investigational therapies: additional information on argenx investigational therapies can be found at www.argenx.com. Our most advanced investigational therapy is efgartigimod (ARGX-113). In June 2018 argenx announced receipt of guidance from the U.S. Food & Drug Administration (FDA) following an End-of-Phase 2 meeting for efgartigimod in generalized myasthenia gravis (gMG). In 2018 argenx initiated a randomized, double-blind, placebo-controlled, multicentre trial enrolling 150 gMG patients in North America, Europe and Japan to evaluate the efficacy and safety of a 10 mg/kg dose of efgartigimod. The study includes both AChR autoantibody positive and AChR autoantibody negative patients. In addition, patients completing the gMG efficacy and safety study can roll over into an open-label extension study for a period of one year during which all patients may receive efgartigimod. Efgartigimod is also in clinical development for Immune thrombocytopenic purpura (ITP), Pemphigus vulgaris (PV) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

argenx expanded access guidelines: At this time, argenx believes that participation in one of our clinical trials is the most appropriate way to access our investigational therapies. Consequently, we have decided to limit access to our investigational therapies to clinical trials that may include open label extension studies. argenx is developing arrangements for appropriate post-trial provision of investigational therapies. Additional information on argenx clinical trials can be found at https://www.clinicaltrials.gov/. Our expanded access guidelines will be continuously reassessed, and any updates will be provided on our website. Further information on post-trial provision of argenx investigational drugs may be obtained by physicians conducting argenx sponsored clinical trials by writing to expandedaccess@argenx.com.