Pfizer Inc. ("Pfizer") is providing additional context related to the August 25, 2017 wholesale acquisition cost ("WAC") price for MYLOTARG (gemtuzumab ozogamicin), listed in MYLOTARG's schedule of WAC increases for the previous five years.

MYLOTARG is indicated to treat CD-33 positive acute myeloid leukemia ("AML"), a rare disease. Due to its target, CD-33, MYLOTARG can be used to treat a range of AML patients and can provide significant benefits for both newly diagnosed and relapsed/refractory AML. MYLOTARG is also an option for children 2 years and older with relapsed/refractory AML and elderly patients who are ineligible for intensive chemotherapy. Manufacturing anti-body drug conjugates is complex and Pfizer has a specialized team and facility to do so.

MYLOTARG's five-year WAC history indicates that, in 2017, MYLOTARG had an increase in its WAC. However, it is important to note that MYLOTARG was not available in the U.S. from 2010 until 2017. MYLOTARG was approved in 2017 by the federal Food and Drug Administration ("FDA") under a new label, offering a new treatment option for AML patients. As a result, MYLOTARG's 2017 WAC was the WAC used when MYLOTARG was re-introduced into the market, after receiving a new regulatory approval.

Pfizer believes the overall cost per patient for the treatment of AML is the most appropriate way to evaluate the WAC of Mylotarg. Most patients will receive only one cycle of MYLOTARG, which is three vials over one week, for $25,338. In 2010, before the product was withdrawn, the list price of MYLOTARG was $15,522 per course of treatment (MYLOTARG was previously approved as two doses [3 vials per dose]) of 9 mg/m2 given 14 days apart, totaling 6 vials). The smaller number of vials currently used helps to reduce, in a significant manner, the difference between the list prices in 2010 and 2017 for a course of treatment. Further, the list price may not be reflective of the cost a patient or a payor ultimately pays for MYLOTARG. Because MYLOTARG is often administered in a hospital inpatient setting, we expect few patients to have out of pocket costs for the medicine. The treatment cost of MYLOTARG is less than the total cost for other recently approved therapies for AML.

In the 7-year period, when MYLOTARG was not otherwise available in the U.S., Pfizer remained committed to MYLOTARG and continued to manufacture and supply it so that it would be available for research in clinical trials. Due to the critical unmet need for patients with AML, there remained great interest among AML clinicians to further evaluate MYLOTARG, with Pfizer's support. Pfizer established an expanded access study in the U.S. designed to allow compassionate access to MYLOTARG for treatment of patients with relapsed/refractory AML. In light of the evidence and support from the community, Pfizer worked closely with the clinical investigators to ensure the new submission met regulatory standards.