AST Statement on Use of Monoclonal Antibody for Pre-Exposure Prophylaxis

Tixagevimab and cilgavimab (Evusheld, AZD7442) received FDA emergency use authorization for COVID-19 pre-exposure prophylaxis in adults and children age 12 and older and who weigh at least 40 kg and who have moderate to severe immunocompromise or a medical contraindication to vaccine. AZD7442 has a longer half-life compared to other currently used antibody preparations (e.g., sotrovimab, casirivimab/imdevimab). The PROVENT trial has shown a 77% reduction of infection in the AZD7442 group compared to placebo up to 183 days. Data are awaited for duration of protection beyond 6 months, effectiveness specifically in the transplant population, and activity against the omicron variant. AZD7442 is not currently indicated for post-exposure prophylaxis or early treatment. At this time, the supply of this agent is anticipated to be limited with an initial availability of 700,000 doses in the U.S. The US military will receive 100,000 doses, and the remaining 600,000 doses will be distributed to state governments which will determine allocation protocols within each state, respectively.

The following provides a framework to help transplant centers plan for allocation of this monoclonal within their institutions:

- **Monoclonal antibody (mAb) therapy should NOT be used as a substitute for vaccination or for primary prevention strategies, including masking, social distancing, and avoidance of large indoor social gatherings.**
    - Vaccination of close contacts, including household members, continues to be an important measure to protect transplant recipients from COVID-19 infection

- Given the limited supply, centers should consider allocating AZD7442 based on stratification of individual patient risk. Risk assessments should incorporate both underlying patient risk factors for severe outcomes from COVID-19 infection as well as risk of exposure to COVID-19 infection.

Risks Associated with Severe disease[1]

- Anti-RBD seronegativity after a complete series of vaccine[2]
- Age ≥ 60
- 2 or more comorbidities[3]
- Lung transplantation
- Immunosuppression (recent B-cell depletion e.g., rituximab; T-cell depletion e.g., ATG, alemtuzumab; Belatacept use)

Risks Associated with Increased Exposure[4]

- High-risk occupations especially schools, day cares, health care
- Residence in a long-term care facility or other congregate setting (e.g., dormitory, prison)

1- Not a comprehensive list

2- Access to serologic testing may not be routinely available to all transplant recipients. Centers choosing to use serologic testing to risk stratify should ensure equity in access to serology. Healthcare funding bodies should ensure serology is available free of cost to patients in order to rationalize the use of pre-exposure mAb.

3- Includes BMI≥30, hypertension, diabetes, chronic kidney disease, chronic lung disease, congestive heart failure, neurodevelopmental disorders

4- Especially if masking and vaccination rates in these areas are low

v. December 13, 2021