

# PolyPid Policy for Expanded Access of D-PLEX

POLYPID is dedicated to developing D-PLEX, a new formulation of Doxycycline for local administration that intended for prevention of Surgical Site Infections (SSI's). The product has a positive impact on patients' health and health care system.

POLYPID is committed to making the investigational product (D-PLEX) available for prevention of infection in seriously ill patients. A treating surgeon, who is able to comply with the requirements that are stated in this document, may request information about how to apply for access to D-PLEX by contacting POLYPID. D-PLEX is currently in Phase 3 clinical development stage with ongoing Phase 3 studies in (1) prevention of SSI post cardiac surgery with median sternotomy and (2) in prevention of SSI post abdominal surgery, with sufficient data available to determine an appropriate dose and schedule for the patient's specific condition.

The purpose of this policy is to describe the requirements for Expanded Access to D-PLEX to patients outside of a clinical study.

## Scope

This policy aims to provide route of access to D-PLEX that is not approved for any purpose in the country from which the request is intended to be used. This also includes the time period between regulatory approval of an investigational product and its commercial availability in a country.

## Policy Statement

Any use of D-PLEX outside a clinical study in the USA must be in accordance with local laws and regulations governing such programs, including POLYPID policies and procedures.

In general, where permitted by local regulation, the investigational product supplied via Expanded Access may no longer be provided by POLYPID when it becomes available via the local healthcare system.

## Policy

We are privileged to collaborate with clinical investigators and with patients who participate in our studies to develop new, safe and effective therapies. At the same time, we understand that there are seriously ill patients who will not be eligible for our clinical trials and may be in a high risk to experience an infection post a surgical intervention. In these circumstances, POLYPID will consider providing the requesting

surgeon with pre-approved access to D-PLEX, for the prevention of infection of an individual patient outside of a clinical trial, when certain conditions are met. These conditions include the following:

- The patient is scheduled for an abdominal or a median sternotomy surgery for any reason.
- The patient is not eligible to participate in POLYPID clinical trials;
- The patient has a serious or life-threatening illness or condition and his/her likelihood to develop a serious infection due to surgical intervention is high;
- The patient has a disease or condition for which there is sufficient evidence of a projected benefit from the use of the D-PLEX and the benefit outweighs the known or anticipated risks;
- A benefit-risk analysis, based on both the available clinical data as well as the requesting surgeon's assessment of the individual patient's condition and history, supports making the investigational drug available;
- Making the investigational drug available will not negatively impact or delay the conduct of clinical trials or a regulatory review or an approval of the investigational drug for broader patient access; and
- Adequate supply of the investigational drug is available and can be supplied in the appropriate timeline of request.

D-PLEX will be applied as per POLYPID instructions.

We continually evaluate the benefit-risk profile of D-PLEX based on evolving clinical data. Requests will be considered on a case-by-case basis.

POLYPID is committed to evaluating all requests in a fair and equitable manner. All requests must be submitted by the patient's treating surgeon; POLYPID may require more detailed information in order to fully evaluate a request. The requesting surgeon must agree to obtain appropriate regulatory and ethics committee approvals and comply with regulatory obligations, including obtaining patient consent, patient monitoring and safety reporting. Each request will be given careful consideration by POLYPID whose decisions are final.

Surgeons seeking pre-approval access for patients should submit their requests to [clinical@polypid.com](mailto:clinical@polypid.com). We regularly monitor this mailbox and will use our best efforts to acknowledge each submitted request within 3 business days after receipt.