Department for Environment, Food and Rural Affairs

Part B: Information about the release application to be included on the public register

B1 The name and address of the applicant

ILiAD Biotechnologies Inc.

4581 Weston Road, Suite 260, Weston, FL USA 33331

B2 A general description of the genetically modified organisms in relation to which the application is being made

Genetically attenuated strain of *Bordetella pertussis* (BPZE1)

B3 The location at which the genetically modified organisms are proposed to be released

The planned clinical trial (Ph-3, study number IB-302P) will be conducted at the following sites in England:

Site name	Address
hVIVO Canary Wharf	40 Bank Street, London E14 5NR
hVIVO Plumbers Row	21 Plumbers Row, London E1 1EQ

B4 The purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put)

The GMO, BPZE1, is a live attenuated *B. pertussis* intranasal vaccine that is being studied in a clinical trial in healthy adults, as a follow-up to a previously successful suite of Phase 2 studies in 719 children and adults, including a virulent challenge study. This Phase 3 virulent challenge study will investigate colonisation rates, immunologic response and the safety of BPZE1 vaccination to potentially protect against colonising, wild-type *B. pertussis* infection in healthy adults using a virulent challenge model.

Current pertussis vaccines (called acellular pertussis vaccines) do not protect against *B. pertussis* infection and therefore the ability to continue to transmit the bacteria to close contacts is a major cause of epidemic outbreaks (which occur every 3-5 years). Following BPZE1 intranasal administration, the live attenuated vaccine is

transiently retained in the upper respiratory tract where it induces immunity. It cannot cause whooping cough due to the genetic changes as part of the vaccine design. The mucosal immunity induced by BPZE1 is targeted to reduce *B. pertussis* infection in immunised individuals, and by doing so can avert person to person transmission. The commercial opportunity is to gain regulatory licensure to vaccinate adults and children against pertussis, and perhaps eventually immunize infants.

B5 The intended dates of the release

June 2026 – June 2036

B6 The environmental risk assessment

The preliminary risk assessment for this study suggests there is an extremely low risk for potential environmental impact associated with administering BPZE1 to study subjects. There is no known animal vector or reservoir for *B. pertussis* outside of humans; it does not exist in soil, on plants or in water. Its colonisation is strictly limited to respiratory tract of humans and is non-invasive (e.g. does not enter blood or other organs), even in immune-compromised subjects.

B7 The methods and plans for monitoring the genetically modified organisms and for responding to an emergency

Samples will be taken from the nose at key time points to ensure that the GMO has a limited survival and clears in all subjects. In all study subjects to date, the GMO has cleared within 45 days, with most subjects having evidence of no BPZE1 within 28 days following vaccination.

In summary, the GMO is readily sampled and identified, and the colonization and clearance behaviour has been consistent and controlled over a typically < 28-day duration.

Efficient antibiotic (macrolide) treatment can be administered. As such, the risk assessment shows a clear and effective emergency response in the unlikely situation that BPZE1 is transmitted to a non-study participant, or BPZE1 has prolonged colonisation.