SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
ORAL POLIOMYELITIS VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
The live oral polio vaccine (OPV) is a trivalent vaccine containing suspension of types 1, 2 and 3 attenuated poliomyelitis viruses (Sabin strains) prepared in primary monkey kidney cell. Each dose (2 drops = 0.1 ml) contains not less than $10^{6.0}$ infective units of type 1, and $10^{5.0}$ of type 2, $10^{5.8}$ of type 3. Sucrose is used as a stabilizer. OPV may contain trace amounts of not more than 2 mcg erythromycin and not more than 10 mcg kanamycin.

3. PHARMACEUTICAL FORM
Solution for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Prophylactic immunization against Poliomyelitis

4.2 Posology and method of administration

**Immunization schedule**
Infants should receive at least three doses of OPV at minimum intervals of 4 weeks. WHO recommends the following schedule in endemic countries: Birth, 6, 10, 14 weeks. In nonendemic areas the first dose can be given from 6 weeks with the first dose of DTP. OPV can be given safely and effectively at the same time as measles, DTP, DT, Td, TT, BCG, Hepatitis B, *Haemophilus influenza* type b, yellow fever vaccine and vitamin A supplementation.

**Administration**
OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi-dose vial by dropper or dispenser. For older children it may be preferred to avoid the possible bitter taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi-dose dropper with saliva of the vaccinated child. Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of OPV from which one or more doses of vaccine have been removed during an immunization sessions may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: *The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09*):
• The expiry date has not passed;
• The vaccines are stored under appropriate cold chain conditions;
• The vaccine vial septum has not been submerged in water;
• Aseptic technique has been used to withdraw all doses;
• The vaccine vial monitor (VVM), if attached, has not reached the discard point (see figure).

4.3 Contraindication
No adverse effects are produced by giving OPV to a sick child. In case of diarrhea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

Immune deficiency
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with OPV according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

4.4 Special warnings and precautions for use
N/A

4.5 Interaction with other medical products and forms of interaction
N/A

4.6 Pregnancy and lactation
N/A

4.7 Effects on the ability to drive and use machines
N/A

4.8 Undesirable effects
In the vast majority of cases there are no side effects. Very rarely, there may be vaccine associated paralysis (one case per 1 million doses administered). Persons in close contact with recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

4.9 Overdose
N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
N/A

5.2 Pharmacokinetic properties
N/A
5.3 Preclinical safety data
   N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
   Kanamycin, Erythromycin, Sucrose in BME (Basal Medium Eagle, 35% v/v)

6.2 Incompatibilities
   N/A

6.3 Shelf life
   2 years from the date of manufacture.

6.4 Special precautions for storage
   Vaccine is potent if stored at not higher than – 20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°C. The vaccine supplied in plastic tubes may change colour due to storage with dry ice; however this does not affect the quality of the vaccine.

6.5 Nature and contents of container
   The vaccine comes in vials of 10 doses and 20 doses

6.6 Special precautions for disposal and other handling
   N/A

7. MARKETING AUTHORISATION HOLDER
   BioNet-Asia Co., Ltd.

8. MARKETING AUTHORISATION NUMBER(S)
   2C 4/53(B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHOURISATION
   May 26, 2010

10. DATE OF REVISION OF THE TEXT
    N/A