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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Lipomed AG, Fabrikmattenweg 4, 4144 Arlesheim, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products;

that the manufacturing licence is including following types of active pharmaceutical ingredients (APIs):

- highly active or sensitising APIs such as Cladribine
- investigational active pharmaceutical ingredients

that the company is performing the following activities:

- primary packing of medicinal products (non-sterile), restricted to investigational medicinal products
  - including solid dosage forms

- secondary packing of medicinal products including randomisation of medicinal products for clinical trials

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **November 14-16, 2018**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products sold in Switzerland.

Berne, January 31, 2019
No. 19-0084

Swissmedic, Swiss Agency for Therapeutic Products

[redacted]

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products
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