

Additional File 1

List of authorities involved in the approval of the trial.

Competent Ethics Committee (“Federführende Ethikkommission”):

- State Chamber of Medicine in Rheinland-Palatinate (Ethikkommission der Landesärztekammer Rheinland-Pfalz), Deutschhausplatz 3, 55116 Mainz

Local Ethics Committee (“Beteiligte Ethikkommission”):

- Chamber of Medicine Westfalen-Lippe (Ethikkommission der Ärztekammer Westfalen-Lippe), Gartenstr. 210 – 214, 48147 Münster

National Competent Authority for the approval of clinical drug trials in Germany:

- The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn