

# NORTH WEST PERSON PROTECTION COMMITTEE III

CHU - level 03 - door 03-363  
14033 Caen cedex 9

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Caen, September 18, 2019

CHRU (Research Department)  
for the attention of Karine FEVRE  
75475 Paris

Ref. CPP: 2019-41

EudraCT number: 2019-001530-33

Ref. promoter: TOPGUN

Ref. CNRIPH: 19.03.28.46025

Category 1 MED

Mrs,

The NORTH WEST III CPP, by deliberation dated June 29, 2019, after having taken note of the conclusions of the pediatric expert, issued a conditional favorable opinion concerning the above-referenced protocol, entitled "TOPGUN study: Evaluation of the efficacy and tolerance of sirolimus in local application on microcystic lymphatic malformations of the tongue. Pilot study in adults and children "and coordinated by Dr. Annabel MARUANI [Tours].

Seated together on June 29, 2019, under the chairmanship of Ms. Charlotte GOURIO,

## Members of the first college

under 1 ° of article R.1123-4 of the CSP

- Mr. Rémy MORELLO, qualified person because of his competence in biostatistics or epidemiology, full member,
  - Mr. Jean-François HERON, doctor, full member,
  - Mr. Claude BAZIN, doctor, full member,
- under 3 ° of article R.1123-4 of the CSP
- Ms. Charlotte GOURIO, hospital pharmacist, Chairman of the committee, full member,
  - Ms. Valérie AUCLAIR, hospital pharmacist, substitute member,

## Members of the second college

under Title 1 of Article R .1123-4 of the CSP

- Mr. Hervé PLATEL, person qualified in the ethical field, full member, under title 3 ° of article R .1123-4 of the CSP
  - Ms. Sylvie BALP, technical advisor to the deputy general directorate of solidarity of the General Council of Caen, full member,
- under title 4 ° of article R .1123-4 of the CSP
- Ms. Fanny ROGUE, lecturer at the Faculty of Law of Caen, vice-president of the committee, full member,
- under Title 5 of Article R .1123-4 of the CSP
- Mr. Alain INGOUF, representative of an approved association of patients or users of the health system, alternate member,

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## Deliberation

Considering the following documents:

- response letter dated July 26, 2019 and signed,
- protocol, English version 1.2 of July 26, 2019,
- summary, French version 1.2 of July 26, 2019,
- information document (parents of minor children), version 1.1 of July 26, 2019,
- information document (children aged 5 to 12), version 1.1 of July 26, 2019,
- information document (adolescents aged 13 to 17), version 1.1 of July 26, 2019,
- information document (adolescents who have reached the age of majority), version 1.1 of July 26, 2019,
- information document (adult patients), version 1.1 of July 26, 2019,
- consent form (parents of minor children), version 1.1 of July 26, 2019,
- consent form (adolescents who have reached the age of majority), version 1.1 of July 26, 2019,
- consent form (adult patients), version 1.1 of July 26, 2019,
- ANSM authorization dated May 24, 2019,
- shooting protocol, version 01,
- patient logbook, version 01,
- participation card, version 01,

the CPP NORD OUEST III therefore opted for:

DEFINITIVE FAVORABLE OPINION

Please accept, Madam, my best regards



Mme Charlotte GOURIO  
Presidente