

Your NHP expert partner for preclinical research

Solution provider for exploratory research in pharmacology, early safety and efficacy studies

Key highlights



2008

Incorporation

Privately owned



Lyon, France

HQ & Facility

Secure supply of NHPs 2025-2028

Full accreditation since 2015



Brand new unique state-of-the-art facility

BSL 1-3, GMO (C1-2)



25 employees

3 DVM, 3 PhD, 9 MsC

+ Network of preferred partners

CNS, Infectious, Bioanalytical capabilities

> 70

Scientific publications & contributions

Non-clinical services

non-GLP

GLP

Exploratory DMPK & early tox

in 2026

PoC studies

Sponsors worldwide

Big Pharma, Biotechs, Start-ups, Research organizations

1 tested COVID-19 vaccine approved



General presentation - Confidential

2

Science-driven preclinical CRO





Core expertises

- NHP model: 15+ years of in-depth expertise and experience
- DMPK and Early Tox
- Infectious & respiratory infectious diseases
- CNS disorders



Strengths

- Highly skilled and experienced team
- Flexible, agile
- Scientific and technical advice
- Flexible design of protocols
- Close customer relationships



Broad experience with NCEs and biotherapies

- Immunotherapies : mAbs, ADC, oncolytic virus, ...
- Vaccines (prophylactic and therapeutic)
- ATMPs : gene therapies
- Oligonucleotides
- Peptides
- LNP
- Small molecules (CNS, Infectious)



Unique European facility for preclinical research



ANIMAL FACILITIES

500m² of housing (ABSL 1-3) & laboratory space (BSL 1-3)

- NHP capacity: 100 ABSL 1-2, 50 ABSL 3
- Rodent & non-rodent species for infectious studies
- Highly energy-efficient building

ANIMAL WELFARE

Animal welfare, staff health & safety (AAALAC- accredited since 2015) EU-compliant large enclosures, social housing, environmental enrichment

BIOCONTAINMENT

Handling of pathogens BSL 1-3 (virus, bacteria, including aerosols) & GMO C1-3

SECURITY

24/7 CCTV, several alarm systems, strong IT security, local and cloud data backups, 48h autonomous power supply with global UPS...

3 000 M² OF FACILITIES AND OFFICES STATE-OF-THE-ART ANIMAL FACILITIES



With the support









Unique European facility for preclinical research









1 autopsy room, 4 procedure rooms, 1 surgery room (X-ray enabled), 2 sample processing rooms

Quality, ethics and animal welfare





QUALITY ASSURANCE & MANAGEMENT

- GLP-like QMS, GLP accreditation aimed for 2026
- 2 FTE for QA
- SEND conversion, long-term archiving
- Equipment monitoring and metrology



ETHICS MONITORING & APPROVAL



- AAALAC accredited since 2015, full accreditation renewed in 2018 and June 2021
- Fully external & independent IACUC (Ethical committee) for protocol approvals
- Internal Animal welfare body: monthly meetings with a consulting veterinarian



ANIMAL WELFARE

- Behavioral enrichment, healthy nutrition and stress avoidance
- Social housing
- Routine animal training program during acclimation, tailored to protocol
- Most of the handling & sampling on awake animals; limited use of sedation or anesthesia





Non-clinical services & capabilities



Exploratory DMPK & early safety

- Pharmacokinetics incl. central and pulmonary PK
- Pharmacodynamics
- Toxicity (acute & chronic), Toxicokinetics, MTD, DRF
- Immunogenicity
- Biodistribution studies (incl. Gene therapies)
- · Immunotoxicity (TDAR), Neurotoxicity

Proof-of-Concept

CNS, Infectious & respiratory diseases, Inflammation, Immunology

- Clinically relevant efficacy models
- Off-the-shelf or on-demand physiopathological models

Dedicated solutions

- Drugs targeting the CNS & infectious respiratory diseases
- Inhaled products / aerosoltherapies
- Nose-to-brain delivery strategies

EXTENSIVE TRAINING PROGRAMS

For dosing and sample collection on awake animals

SPECIFIC CAPABILITIES

- Advanced surgical capabilities
- Screening capability for gene therapy
- Infectious & respiratory diseases : Ecological **mode of infection**, *rodent & non-rodent efficacy models*
- **Dosing routes**: standard & specific: *Infusion (up to 4/6h), intrathecal (Lumbar, ICM), Intracerebral, Intranasal, Inhalation, intratracheal...*

IN-LIFE

- Clinical pathology
- Clinical, behavioral and neurological assessment: proprietary grid, FOB, cognitive & sensorimotor assessment (cognitive)
- Standard & specific sampling: Blood, CSF, BM, BAL, SWAB, Urine, Feces, Biopsies, tissues & organs (incl. deep brain structures)

BIOANALYSIS

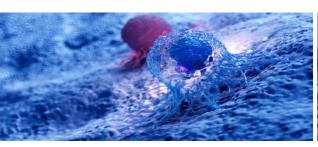
Preferred network of partners

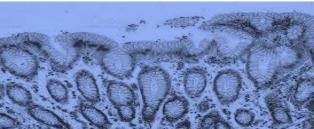
IN VITRO & EX VIVO

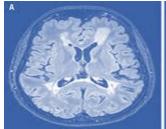
Full package services from in vitro / ex vivo screening to in vivo studies

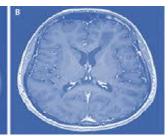
Full service package with bioanalytical capabilities













IMMUNOLOGY

- PK/TK
- Receptor Occupancy
- Immunogenicity
- · Biomarkers of efficacy / PD
- · Biomarkers of safety
- Functional assays
- Development & validation of methods
- · On-demand biomarkers

HISTOPATHOLOGY

- Tissue fixation
- Tissue staining (incl IHC)
- Histopathological evaluation
- · Immunohistochemistry

TRANSLATIONAL IMAGING

- MRI
- MRS (CSI)
- PET
- PET-MRI, CT scanner, µCT scanner,

VIROLOGY MONITORING

- Viremia
 - Viral genome quantification by RTqPCR
 - Infectious titration (TCID50)
- Inflammation
- Immunophenotyping
- Seroneutralization assays
- Biological markers













Respiratory viral infection models in NHP

RSV | hMPV | SARS-COV-2

NHP Model to Evaluate Immunotherapies against hRSV Infection

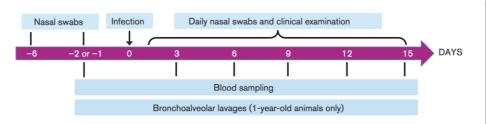


OBJECTIVES

- Immunogenicity , Toxicology
- Viral challenge

METHODS

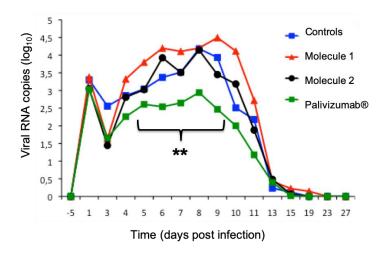
- Biocontainment level : A2
- Infection : IT, IN, aerosolization, nebulization



- Clinical observations (BW, HR, RR), temperature (autonomous logger)
- Sampling: nasal & nasopharyngeal swabs, BAL, urine, blood ...
- Analysis of viral RNA copies of hRSV, cytokines
- Option: organs and tissues collection
- Reference compound: palivizumab

RESULTS

• Upper respiratory tract infection: Viral RNA copies (qRT-PCR)



- Newborn monkeys are not more susceptible to infections than monkeys of standard age
- HRSV-infected animals are protected from reinfection 6 months after 1st injection
- First POC of antiviral efficacy of intranasal Palivizumab

References

Grandin C et al. J Gen Virol. 2015 Apr 96(Pt 4): 782-792. Grandin C et al. Antiviral Res. 2016 Jan 19;125:58-62.

Cited in Sanofi's paper: Swanson K.A et al, Science Immunology, 2020 May, 5 (47).

SARS-CoV-2: Bimervax efficacy study



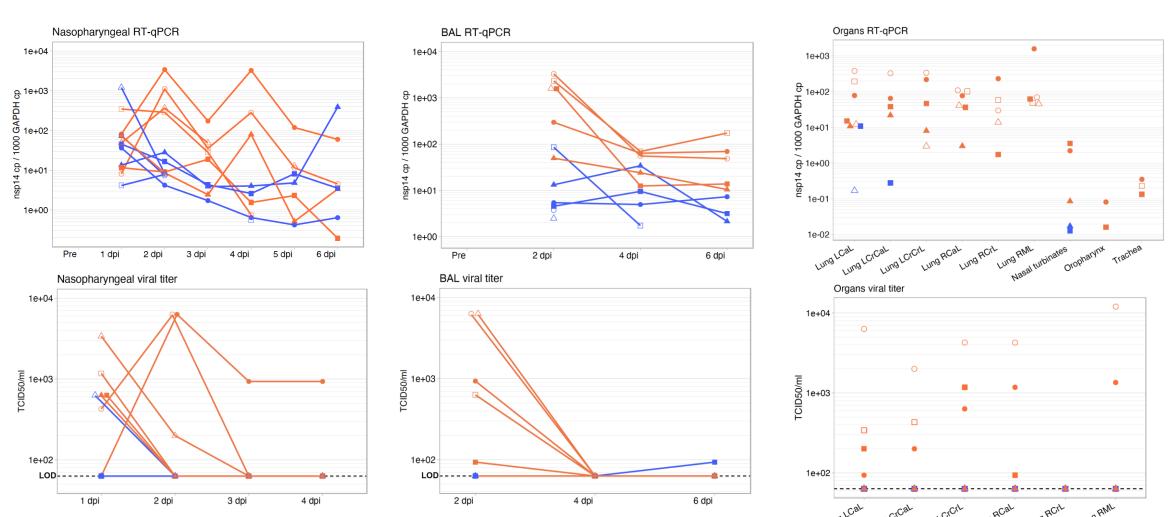
Request by Hipra (Spain) to test preclinical efficacy of a vaccine based on a fusion protein

- 2 groups (6 animals each, 3M/F)
- Prime/boost vaccination
- Infection and follow-up for 7 days
- BAL, swabs, temperature, serum, necropsy.
- Virpath: inoculum, RT-qPCR, TCID50, Seroneut



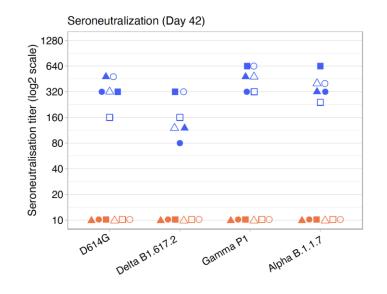
SARS-CoV-2: Bimervax efficacy study

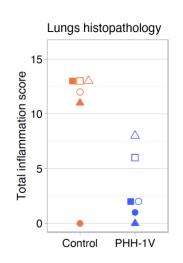




SARS-CoV-2: Bimervax efficacy study









- Clear viral replication in lower and upper airways in control group
- Clear difference in viral load between groups, despite complete blind design
- Clear difference of lung inflammation between groups
- Clear neutralizing efficacy across strains, even against delta variant.
- => EMA authorized phase 2 clinical trial!
- => Publication with HIPRA and VirPath

Prenafeta, A., Bech-Sàbat, G., Moros, A., Barreiro, A., Fernández, A., Cañete, M., Roca, M., González-González, L., Garriga, C., Confais, J., Toussenot, M., Contamin, H., Pizzorno, A., Rosa-Calatrava, M., Pradenas, E., Marfil, S., Blanco, J., Rica, P. C., Sisteré-Oró, M., ... Ferrer, L. (2023). Preclinical evaluation of PHH-1V vaccine candidate against SARS-CoV-2 in non-human primates. IScience, 26(7). https://doi.org/10.1016/j.isci.2023.107224



