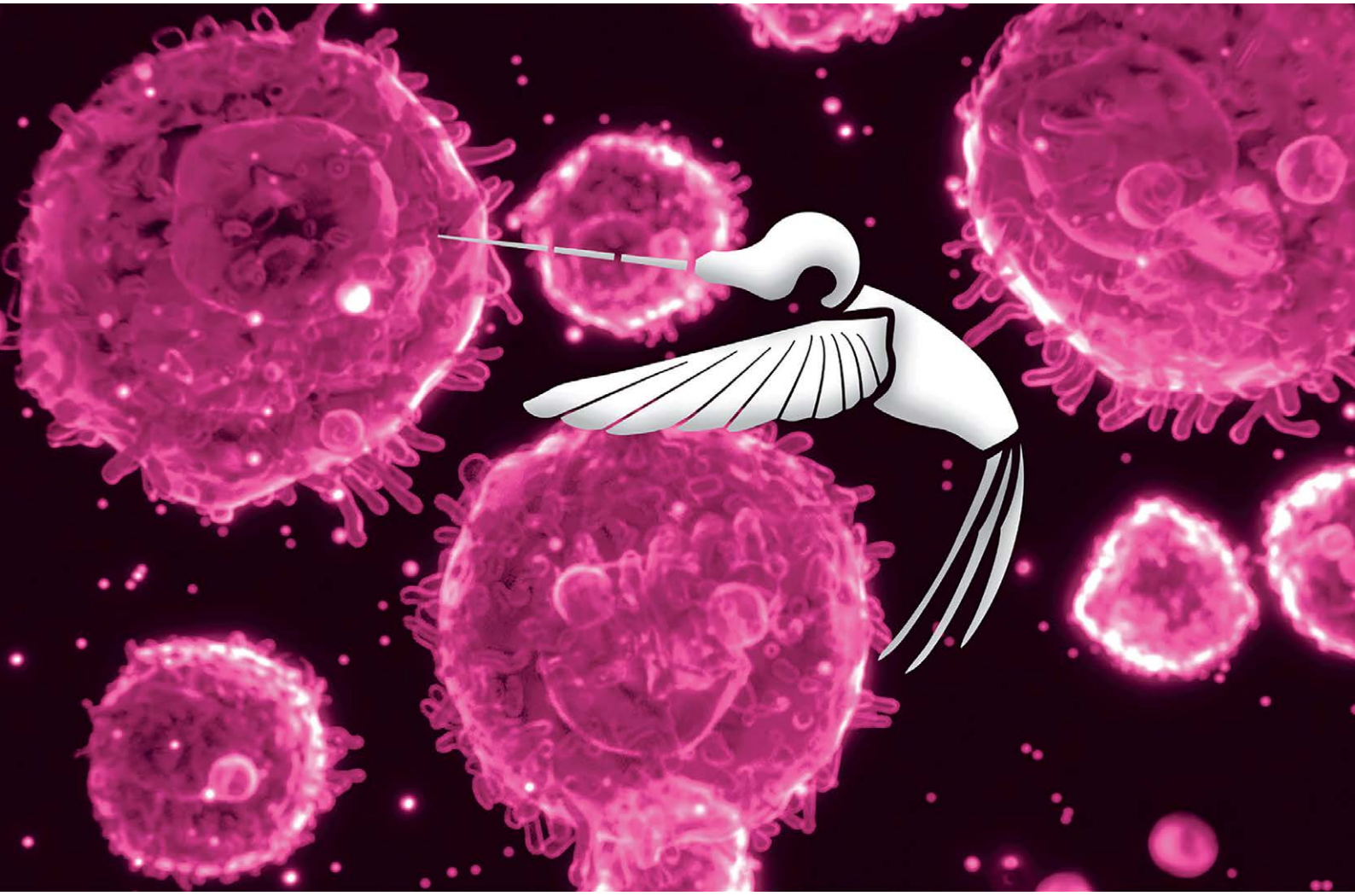
AURIGON
a wing stroke ahead.



VACCINES

AURIGON – YOUR CONTRACT RESEARCH PARTNER

VACCINES

VACCINE CANDIDATES HAVE A SPECIFIC DEVELOPMENT CYCLE THAT DIFFERS FROM OTHER PHARMACEUTICAL PRODUCTS

Aurigon fulfils all requirements and supports you during the in vitro or in vivo non-clinical development of your vaccine candidate by assessing:

- Safety
- Immunogenicity (the ability to provoke an immune response)
- The application method

Non-clinical toxicity testing of vaccines is conducted prior to human clinical trials to evaluate vaccine candidate safety. These studies aim to identify potential toxicities and target organs and to determine a safe dose, including the establishment of a NOAEL if required.

Based on the requirements of the WHO guideline on non-clinical evaluation of vaccines, the parameters to be considered in designing animal toxicology studies are:

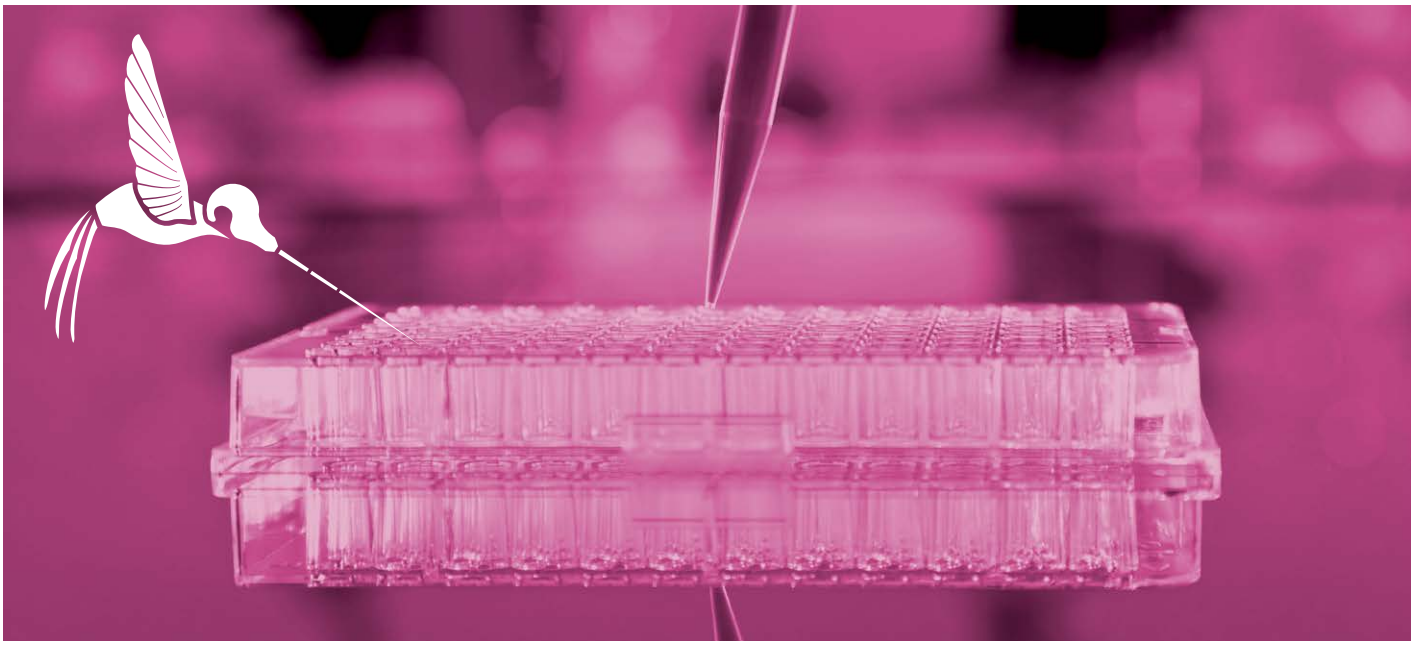
- The relevant animal species and strain
- Dosing schedule & method of vaccine administration
- Timing of endpoint evaluation (e.g. sampling for clinical chemistry, antibody evaluation and necropsy)

The route of administration should correspond to that intended for use in clinical trials. The toxicity assessment of the vaccine formulation in the toxicity studies should also include an assessment of local tolerance.

The wide range of immunoassays we offer enables tailored confirmation of the required immune responses in immunogenicity and toxicity studies.

Our experienced staff and the GLP/GMP-certified testing facility of Aurigon ensure:

- Study designs in accordance with the latest FDA/USP, EMA/Ph.Eur., ICH and WHO guidelines
- Multiple modes of administration including, e.g. intranasal administration
- Animal handling according to the European guidelines and directives and under the control of the Institutional Animal Care and Use Committee



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STUDY LIST

GENERAL TOXICOLOGY

- Repeated-dose toxicity studies
- Local tolerance testing (in vivo)
- Target animal safety studies

IMMUNOGENICITY STUDIES

- In different species and with different immunization schedules

BATCH RELEASE TESTING

- In vitro potency assay of the expression level of protein of interest
- In vitro potency assay of the infectivity of an oral vaccine

RELATED ASSAYS

IMMUNOGENICITY PROFILING

- Anti-drug/target antigen antibody assay (ADA)
- Cytokine/chemokine production
- Immune cell phenotyping
- Intracellular cytokine staining
- Activation-induced surface markers
- Immunohistochemistry of immune tissues
- T-cell proliferation assay

FUNCTIONAL IMMUNOTOXICITY

- Immunotoxicological evaluation of toxicity studies
- T-cell dependent antibody response (TDAR)
- Natural killer cell (NK) activity assay
- Cytotoxic T-cell (CTL) function assay
- Macrophage/neutrophil function assay
- T-cell proliferation assay
- Immune cell phenotyping
- Cytokine release assay
- Complement activation assay
- Complement-dependent cytotoxicity (CDC)
- Acute phase protein measurements
- Immunohistochemistry of immune tissues

VACCINES

Why choose Aurigon?

FOR THE SAKE OF YOUR SUCCESS

- Our qualified staff consists of more than 80 professionals, including colleagues with more than 30 years of experience
- Our proven record of more than 6700 studies gives us a solid base to serve your needs
- Our flexible approach and your direct contact to your Study Director gives you full control of your study
- We are large enough to provide a full service and small enough to fully adapt to your needs

DISCOVER MORE ON www.aurigon.eu

If you need additional information please contact us. We truly hope that the provided information brings you ...

... a wing stroke ahead.

Scan the QR code to get access to our scientific knowledge pool.