REITHERA

Dedicated to

TRANSLATIONAL MEDICINE: from basic science to clinical development

VIRAL VECTORs MANUFACTURING: from bench scale to cGMP production

THE COMPANY

ReiThera is a biotech company dedicated to the technology development, GMP manufacturing and clinical translation of vector gene-delivery platforms by exploiting adenovirus (AdV), Modified Vaccinia Ankara (MVA) and Adeno-associated Virus (AAV)

CDMO

Third-party contracts based on Process Development and/or GMP productions for phase I, II, III

Contracts with both mid-size companies and established organizations

More than 10 executed projects in 2020

R&D Pipeline

Novel GRAd platform for genetic vaccines

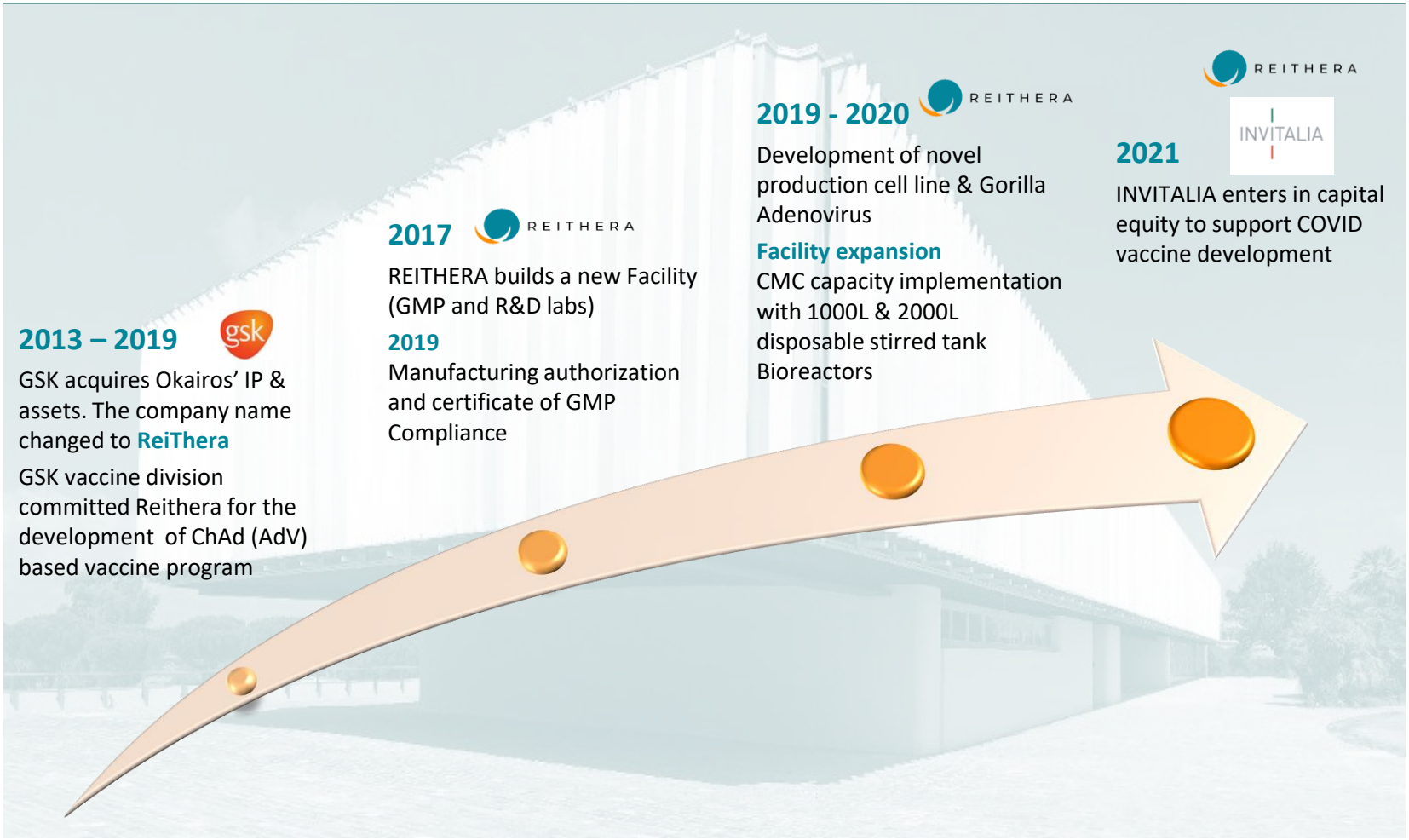
COVID-19 GRAd-COV2 vaccine development started early 2020

GrAd platform validation by preclinical and clinical investigation

Clinical PoC in ph II/III trial started

R&D activities ongoing to address COVID 19 variants and second generation vaccine

LOOKING AT THE FUTURE CAPITALIZING ON A HISTORY OF SUCCESS



REITHERA'S ORGANIZATION & CAPABILITIES

Research Labs
- Vectorology Unit
- Immunology Unit

Preclinical & Clinical Development Unit
- Internal capacity for in vivo & in vitro studies
- Monitoring of external non clinical studies
- Clinical experts dedicated to clinical study design and implementation

Regulatory Affairs Unit
- Preparation of Regulatory documentation
- Interaction with local and central Authorities

Process Development Labs
- Upstream Unit (cell engineering & process scalability) including fixed bed and stirred talk bioreactors
- Downstream Unit (advanced purification technologies)

GMP Facility & QC labs
- Stirred tank bioreactors at 200L, 1000L 2000L
- Fixed bed bioreactors (up to 30 sqm)
- Quality system for DS & DP GMP production and release Unit
- QP in place

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GRAd-COV2

Vaccine Development Overview

14 – 12- 2020

Proprietary Vaccine Platform Technology

ReiThera' vaccine platform is built on 3 pillars

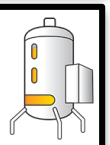
GRAd32 VECTOR

- Novel **group C adenovirus** strain isolated from a captive gorilla
- Related to several clinically validated human and simian Ad vectors (hAd5 and ChAd3)
- **Low seroprevalence** on human sera
- **Strong immunological potency**

ReiCell35S CELL LINE

- **Suspension-adapted packaging/production** cell line derived from low passage (p6) HEK-293 cells
- Detailed history starting from 70's HEK 293 original record
- Silencing of transgene expression: high productivity and low genomic instability

GMP manufacturing



- Large GMP manufacturing facility AIFA approved
- Manufacturing capacity expansion by end 2020
- Process scale up from 200L to 3000L in STR
- Production target:>200 million doses per year from 4Q-20 including fill-finish

GRAd-COV2 VACCINE DEVELOPMENT MILESTONES

1. Preclinical investigation

Preclinical studies in animal models (rodents and rhesus macaques) supported successfully the vaccine candidate in terms of safety and immunogenicity

2. Clinical Phase I

A Phase 1 clinical trial was performed to evaluate the safety and immunogenicity of GRAd-COV2 for 24 weeks in 90 healthy volunteers (HV) divided equally into two age cohorts: 18-55 years and 65-85 years.

Interim results showed that the vaccine is well tolerated and immunogenic

3. Phase II/III clinical ongoing

The phase II is a placebo controlled 3 arms trial involving about 900 HV. In the study a single and double dose regimen will be investigated. The trial is currently ongoing – all volunteers have been vaccinated.

Phase III planned to start in July

CMA planned for mid September/October

Thanks for the attention

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