

### Leads



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### Original Key Objectives of WP7

- Assessment of safety, tolerability, PK and optimal dose of small molecule candidate in a Phase 1 trial (CARE I)
- Assessment of safety, tolerability, PK and optimal dose of an HmAb candidate in a Phase 1 trial (CARE II)
- Assessment of clinical efficacy and/or biological activity of a candidate drug in a Phase 2a trial (CARE III)

### CONNECTIONS

*with other work packages, committees*



#### Work package 1-4

Liaise with WP1-4 regarding possible small molecules or antibody candidates in the pipeline that may be suitable for clinical trial

#### Work package 5

Development of a sampling routine for transcriptomics analyses from blood

#### CARE Governance

Assess all external candidates with potential for clinical trial in CARE, as indicated by the Pipeline Development Scientific Committee (PDSC) and Steering Committee (SCOM)

### Revised Objectives/ Achievements

- Internal antibody and small molecule candidates were not progressed to trial within CARE for logistical and timeline reasons. Two of these antibodies clinically evaluated outside CARE due to manufacturing costs
- Four external antibodies and four external small molecule candidates were assessed for trial conduct in CARE and clinical plans/protocols reviewed – timelines did not fit within CARE timelines
- CARE decision to conduct combination drug trial in immunocompromised patients – an area of unmet need (CLEAR trial) after consultations with EMA and IHI. Set up activities ongoing – timelines in CARE not feasible but funding being sourced to conduct trial outside CARE

### BREAKTHROUGH moments



**2020-23**

**Set up and maintenance of the Clinical Trial Platform**

**Discussion and implementation of quality assurance, fast track processes, patient information/access and representation**

**Conduct of trial network identification survey**

**2024**

**Design of the CLEAR Trial in immunocompromised patients not clearing SARS-CoV-2. Set up activities including protocol writing, site selection**

### PUBLIC DELIVERABLES



D7.16 Set up of the Clinical Trial Platform (CTP) – fast track process set up

D7.17 Set up of CTP – implementation of representation concept completed

D7.18 Set up of CTP – training for new standard operating procedures conducted

### Partner Organisations



NOVARTIS Johnson&Johnson



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