



# Development plan for NeuroRestore ACD856

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# Project pipeline based on cutting-edge proprietary molecules

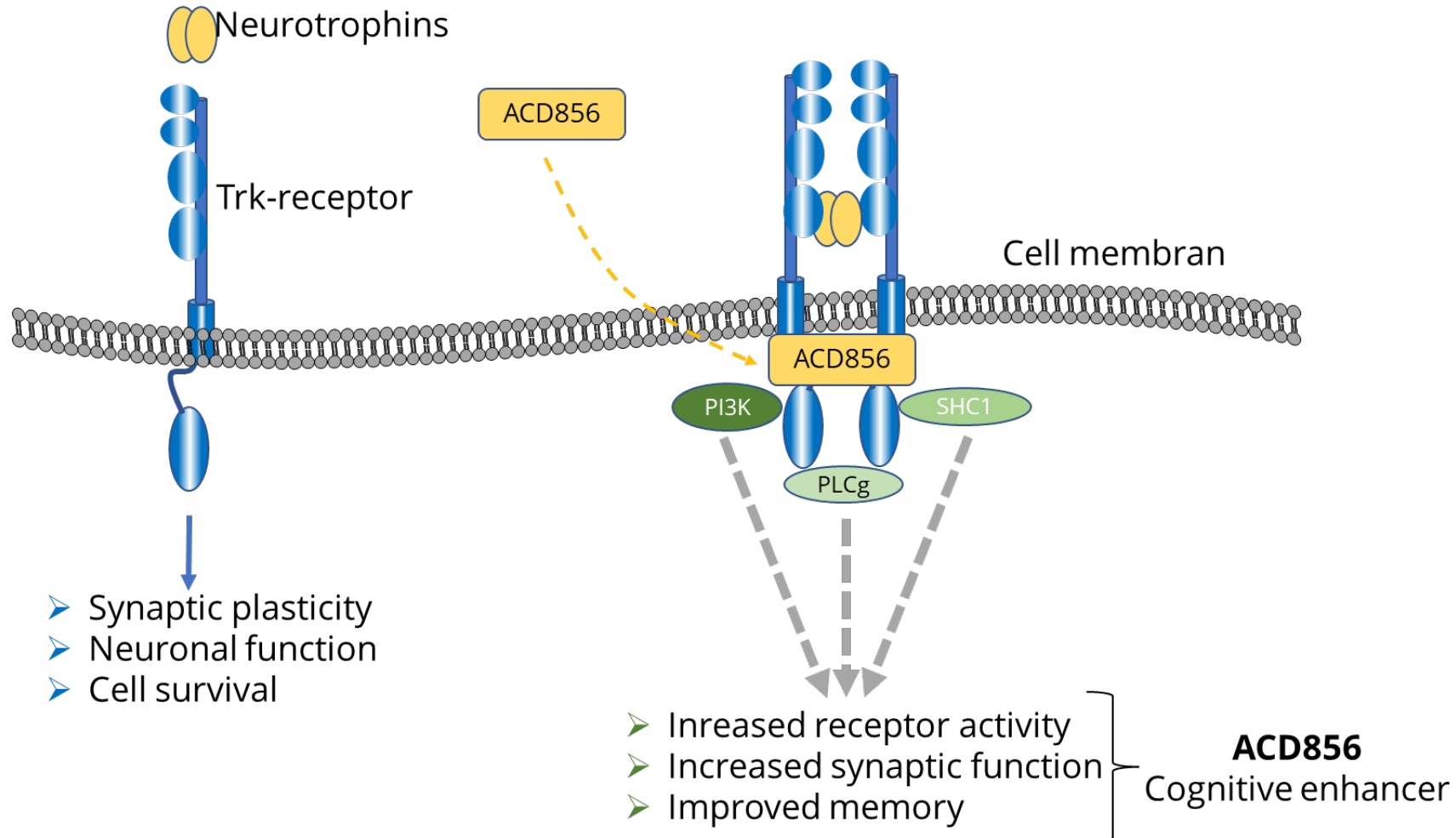
Platform	Candidate	Indication	Research phase	Preclinical phase	Phase I	Phase II	Phase III
NeuroRestore®	ACD856	Alzheimer's Disease, Sleep disorders, Traumatic brain injuries Parkinson's disease					
	ACD857	Alzheimer's Disease					
Alzstatin®	ACD679	Alzheimer's Disease					
	ACD680	Alzheimer's Disease					
Painless	ACD440	Neuropathic Pain					
	TrkA-NAM	Osteoarthritic Pain & other severe pain conditions					

Phase completed

Phase ongoing



# Neurotrophin signalling is vital for normal cell functioning



# BDNF signalling is a genetically validated pathway in AD

## BDNF Val66Met polymorphism

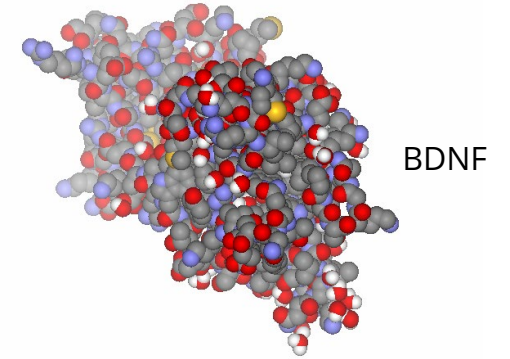
- *Prevalence: 37% of Caucasians, up to 70% of Asians*
- *Result: 30% reduction in BDNF secretion*



**Alzheimer's  
disease**



Increased rates of decline in  
memory and hippocampal  
atrophy



- ✓ ***BDNF plays an important role in the brain's ability to withstand the effects of pathological processes***
- ✓ ***NeuroRestore enhances neurotrophin signaling and could therefore have a positive effect on neuronal and cognitive function in AD***

# NeuroRestore - multiple indications possible for clinical development

## Cognitive dysfunction associated with:

› **Alzheimer's disease**

› **Brain injury/Head trauma**



› **Parkinson's disease**

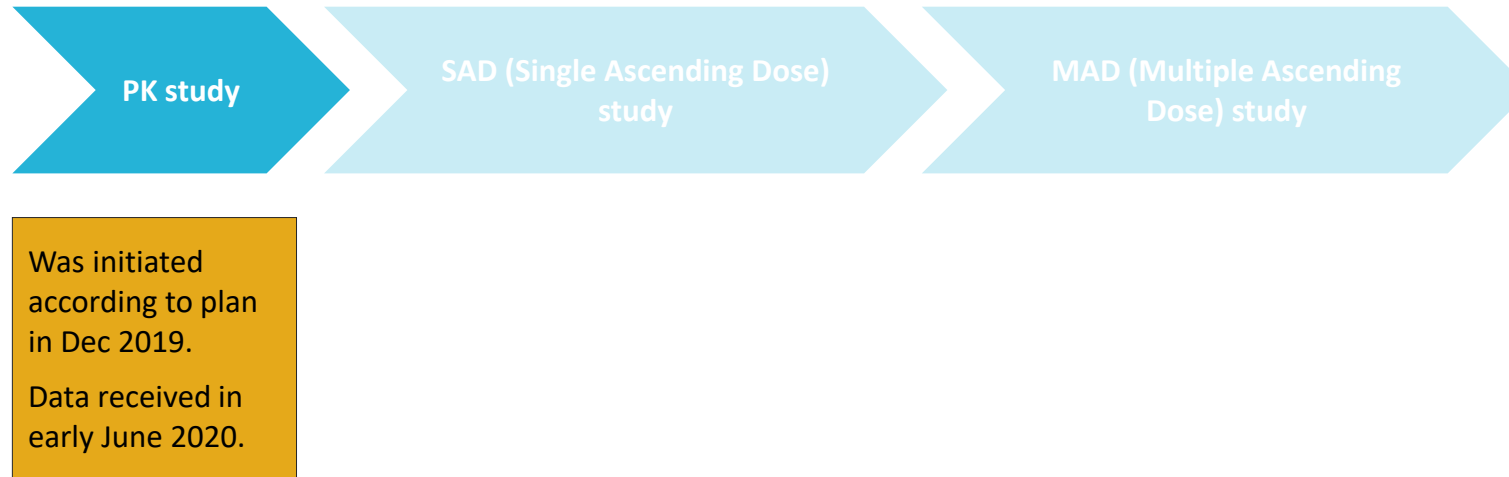
› **Sleep disorders**

› **...but also other indications, such as Depression (Casarotto et al., Cell (2021))**

# Clinical Phase I studies for ACD856



# Clinical Phase I studies for ACD856





# PK study - first clinical study with ACD856

## AlzeCure announces positive data from clinical study with ACD856

June 4, 2020

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of drug candidates for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that the company has received positive results from the first clinical study with ACD856, aiming to evaluate half-life in humans. ACD856 is currently under development for e.g. Alzheimer's disease.

The results demonstrate that ACD856, the lead drug candidate within the company's NeuroRestore platform, has a good pharmacokinetic profile with a significantly shorter human half-life than its predecessor ACD855, as well as a suitability for further clinical development, e.g. in oral treatment of Alzheimer's disease.

### **Primary objective**

- To determine the pharmacokinetic profile of a single administration of ACD856

### **Secondary objective**

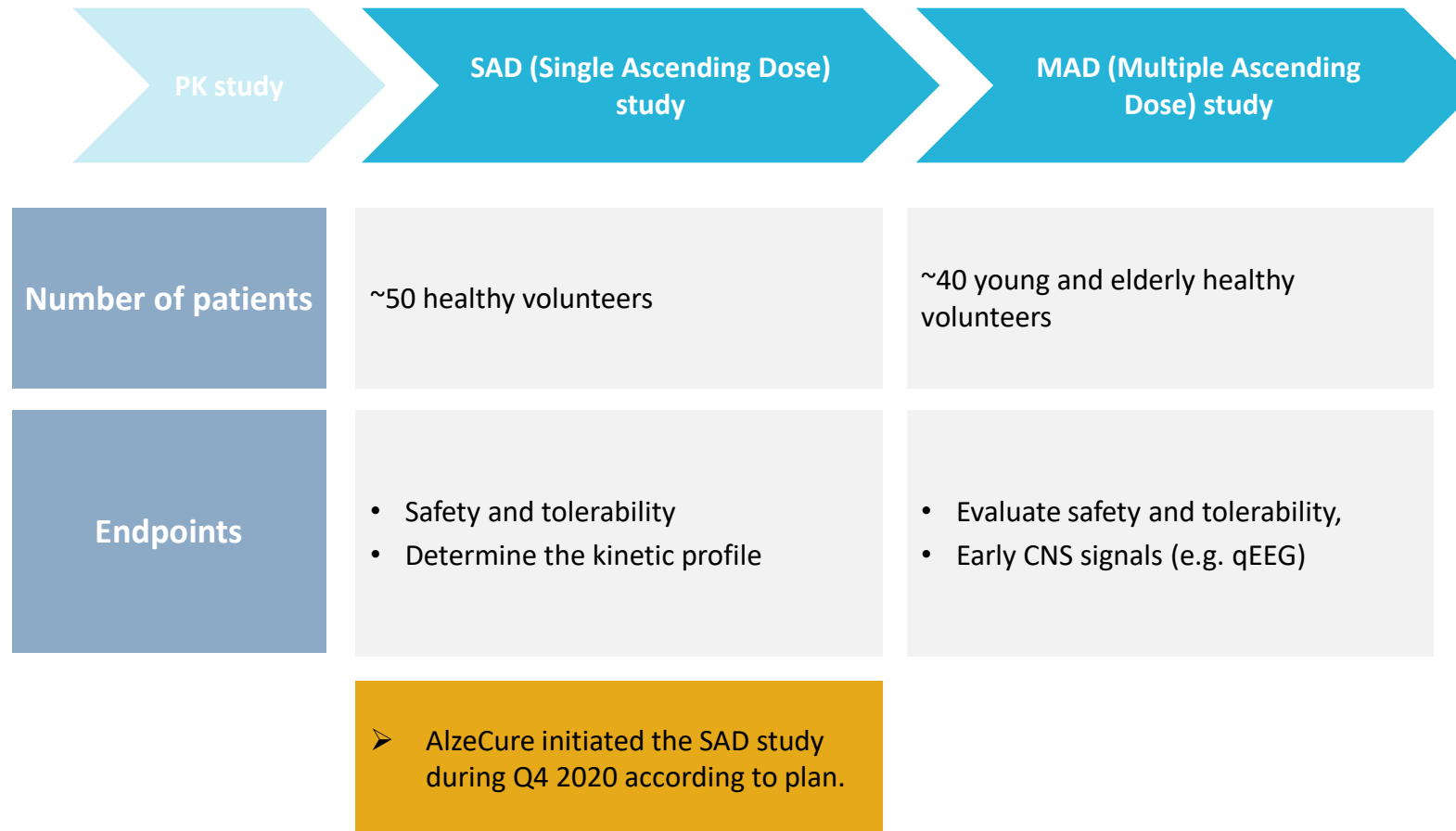
- To evaluate the safety and tolerability of a single administration of ACD856

### **Results:**

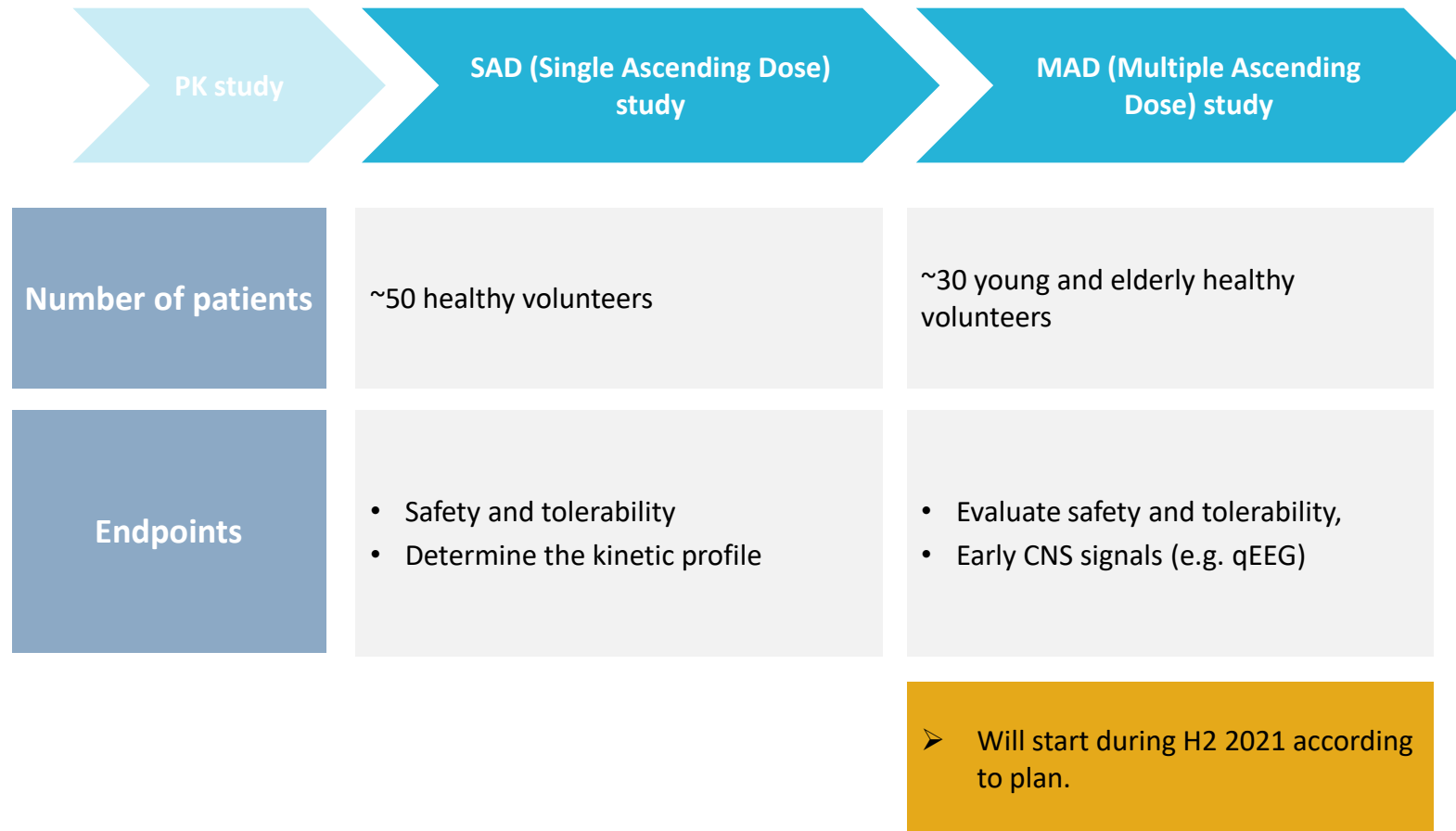
- ✓ **ACD856 was well tolerated and had a suitable half-life for further clinical development**



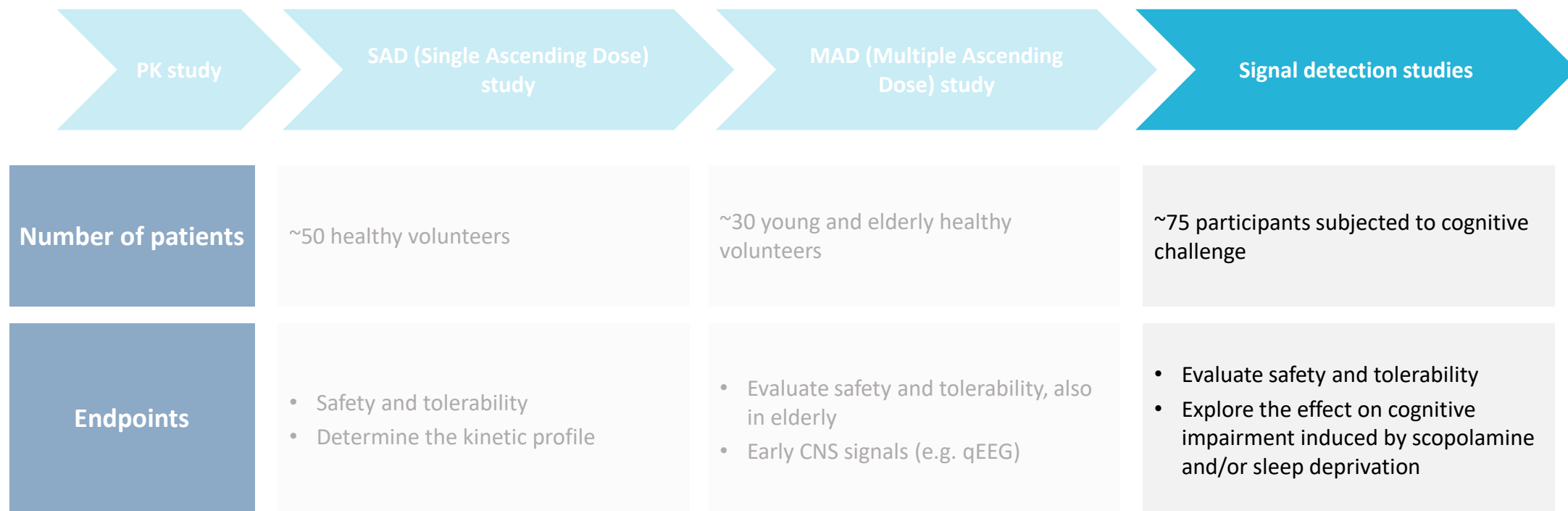
# Clinical Phase I studies for ACD856



# Clinical Phase I studies for ACD856



# Building value - signal detection studies

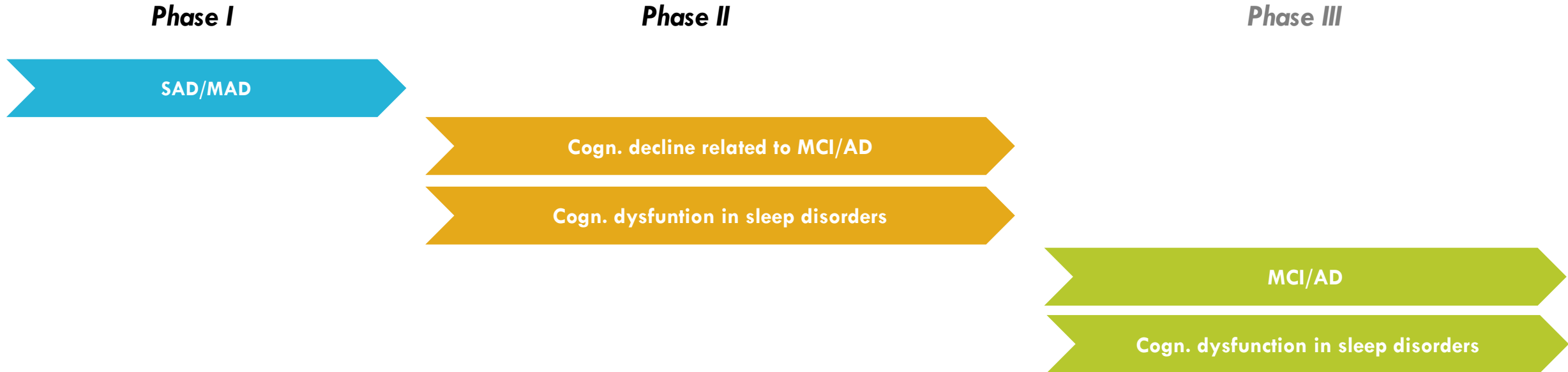


# Early efficacy – adding value to ACD856

- Strong value driver for the project
- Designed in collaboration with KOLs in the field
- Chosen models relevant for the indications of ACD856
- ACD856 will be assessed in models of cognitive dysfunction:
  - Scopolamine
    - Cholinergic dysfunction relevant for AD indication
    - Translation of results from pre-clinical studies
  - Sleep deprivation
    - Considered a proof-of-concept study for sleep disorder indication
    - Sleep impairment is an important co-factor of cognitive impairment also in AD and PD. May open doors in these indications in addition to the sleep disorder indication



# Long-term clinical development plan for ACD856




- **Other cognitive disorders than AD/MCI, e.g. insomnia and sleep apnea, could be a cost-effective and feasible first indication**
- **As indicated, other potential secondary indications are possible e.g.**
  - **Cognitive dysfunction after TBI**
  - **Cognitive impairment in Parkinson's Disease**

# Summary

- ✓ **ACD856 enhances neurotrophic signalling** - a biological system involved in supporting neuronal function incl. cognitive processes
- ✓ **Multiple potential indications** - the mechanism-of-action supports several indications for NeuroRestore
- ✓ **Supportive pharmacological data** - Preclinical in vitro and in vivo pharmacological studies support an effect on neuronal and cognitive function
- ✓ **First clinical study conducted** – the study conducted showed a PK profile appropriate for further clinical development
- ✓ **Second clinical study currently ongoing** – SAD study initiated according to plan in Q4 2020
- ✓ **Next clinical study to start in late fall** – MAD study to be initiated in H2 2021 according to plan
- ✓ **Clinical development plan with potential for early efficacy signals** – novel approach to evaluate early efficacy signals



The image is a composite. In the center, a pair of hands holds a realistic anatomical model of a human brain, showing the cerebral cortex and internal structures. To the left, a translucent, glowing blue neuron with multiple branching processes is superimposed over the background. The background itself is a blurred laboratory setting with various pieces of equipment, including a blue-capped bottle and a white container.

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