LIDDS™

Noviga Research AB

March 18, 2024

Noviga Research in short

- Swedish biotech company founded in 2014
- Focused on developing new pharmaceuticals for advanced cancers
- Noviga's leading compound NOV202 is in pre-clinical development
  - ✓ Has shown promising data in several tumour models
  - ✓ Shows very strong synergistic effects with PARP inhibitors in preclinical in vivo models for ovarian, pancreatic and prostate cancer, both BRCA mutated and BRCA wild-type
  - ✓ NOV202 may have effect on both primary and metastatic malignant brain lesions since it penetrates CNS and is not a PGP substrate
  - ✓ The compound is well tolerated, has good PK properties including oral bioavailability and CMC questions are controlled
  - ✓ Final tox study to be conducted before clinical development
  - ✓ Advisory meeting with Swedish MPA supports completed and planned studies
  - ✓ Both NOV202 and NOV202 in combination with PARP inhibitors have patent protection
- Noviga has a substance library of 200 NOV202 analogues

NOV202 – Effective across a large panel of cancer cells

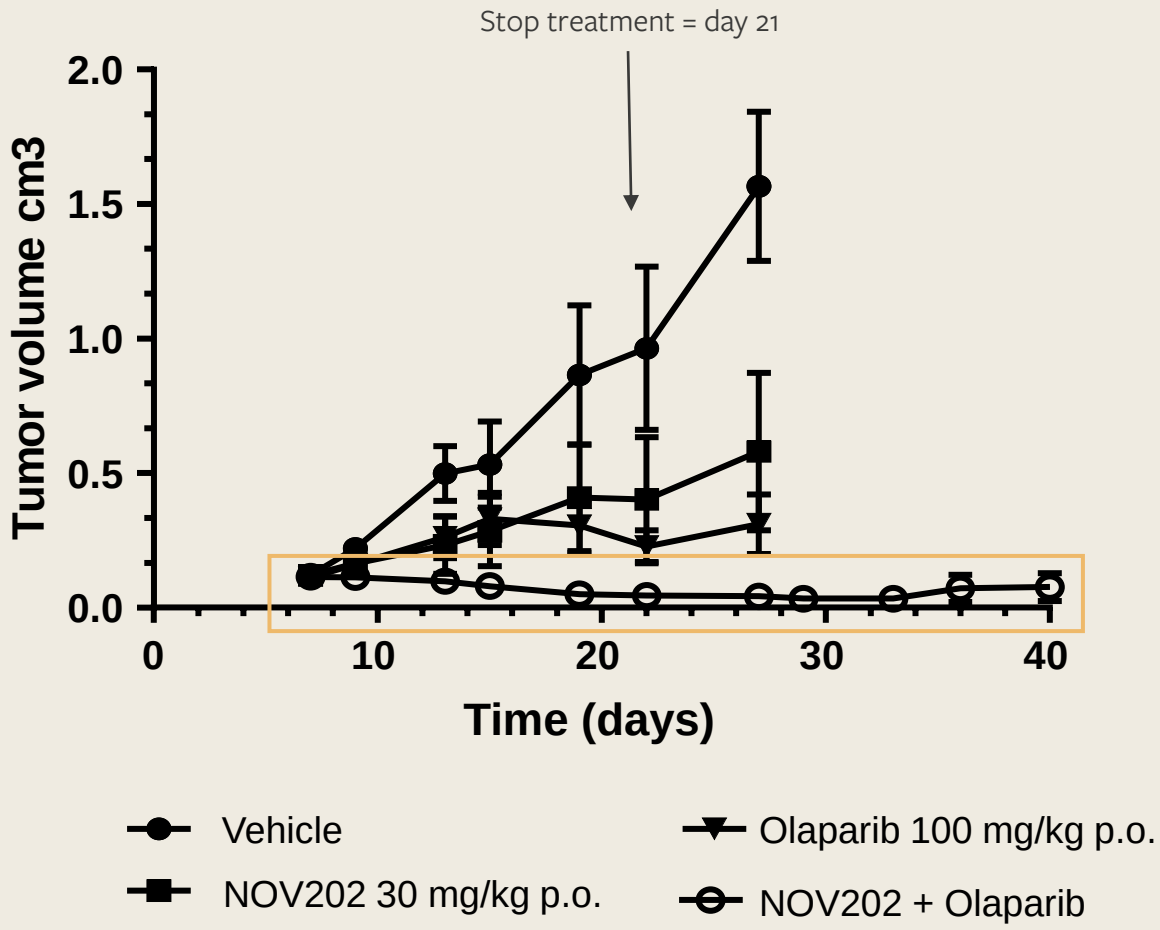
- Effective across a large panel of cancer cells in vitro as **monotherapy**
- IC_{50} is a quantitative measure that indicates how much of a particular inhibitory substance (drug) is needed to inhibit, *in vitro,* a given biological process or biological component by 50%

Disease	Cell line	IC_{50} (nM)
Ovarian carcinoma	A2780	2.4
Pancreatic adenocarcinoma	BXPC-3	8.0
Ovarian carcinoma	CAOV-3	8.0
Acute lymphoblastic leukemia	CCRF-CEM	10.0
Colorectal carcinoma	HCT116	9.2
Cervical adenocarcinoma	HeLa	12.0
Colorectal adenocarcinoma	HT29	3.9
Breast adenocarcinoma	MDA-MB-231	4.2
Ovarian carcinoma	OVCAR-4	14.0
Ovarian carcinoma	OVCAR-8	22.0
Multiple myeloma	RPMI 8226	12.0
Histiocytic lymphoma	U-937	8.0

NOV202 in Combination with Olaparib

Ovarian Cancer PDX BRCA-wildtype model

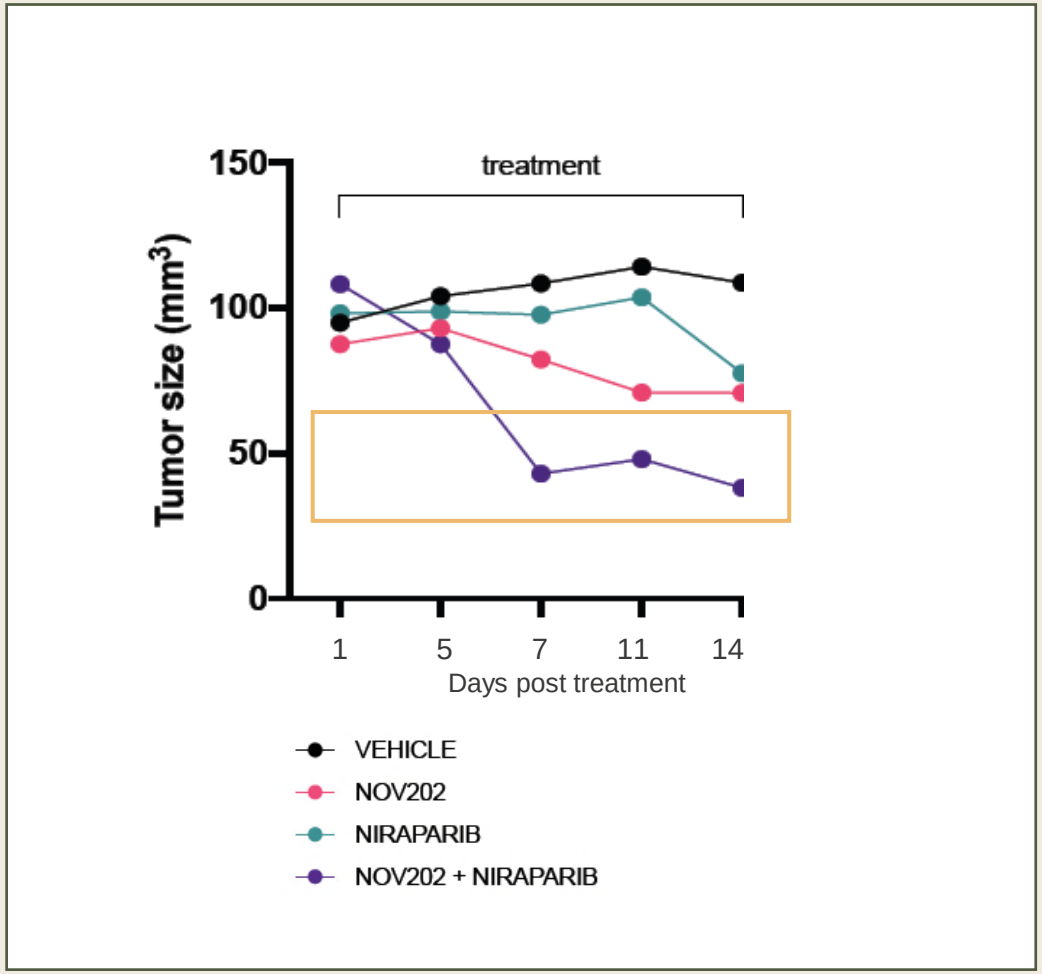
- Daily treatment with both 30 mg/kg NOV202 for 14 days as monotherapy and in combination with Olaparib (PARP inhibitor) was well tolerated.
- Drug administration was stopped on day 22.
- The combination of NOV202 with Olaparib had a distinct synergistic effect.
    - The T/C value was improved to 3 % in the combination group compared to 37 % (NOV202) and 20 % (Olaparib) after monotherapy.
- Tumor remission was almost complete at the end of therapy (mean RTV = 0.4, day 22), and continued until day 40.
- The study was repeated with same results



NOV202 in Combination with Niraparib

Prostate cancer Xenograf BRCA mutated model

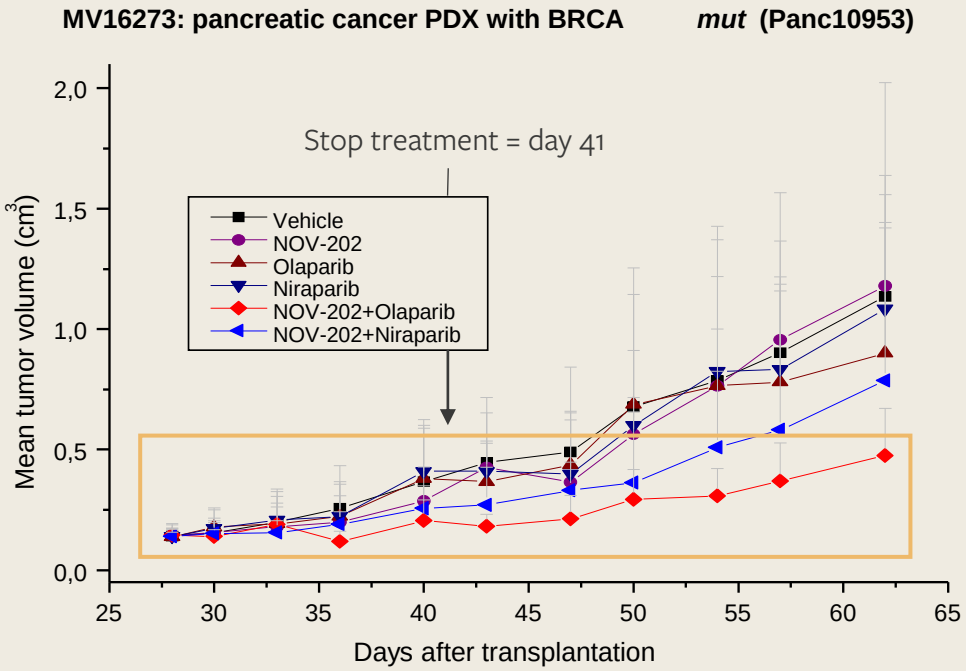
- Daily treatment for 14 days
- The combination of NOV202 with Niraparib (PARP inhibitor) had a distinct synergistic effect.



NOV202 in Combination with Niraparib and Olaparib

BRCA 1/2 Mutated Pancreatic Cancer PDX Model

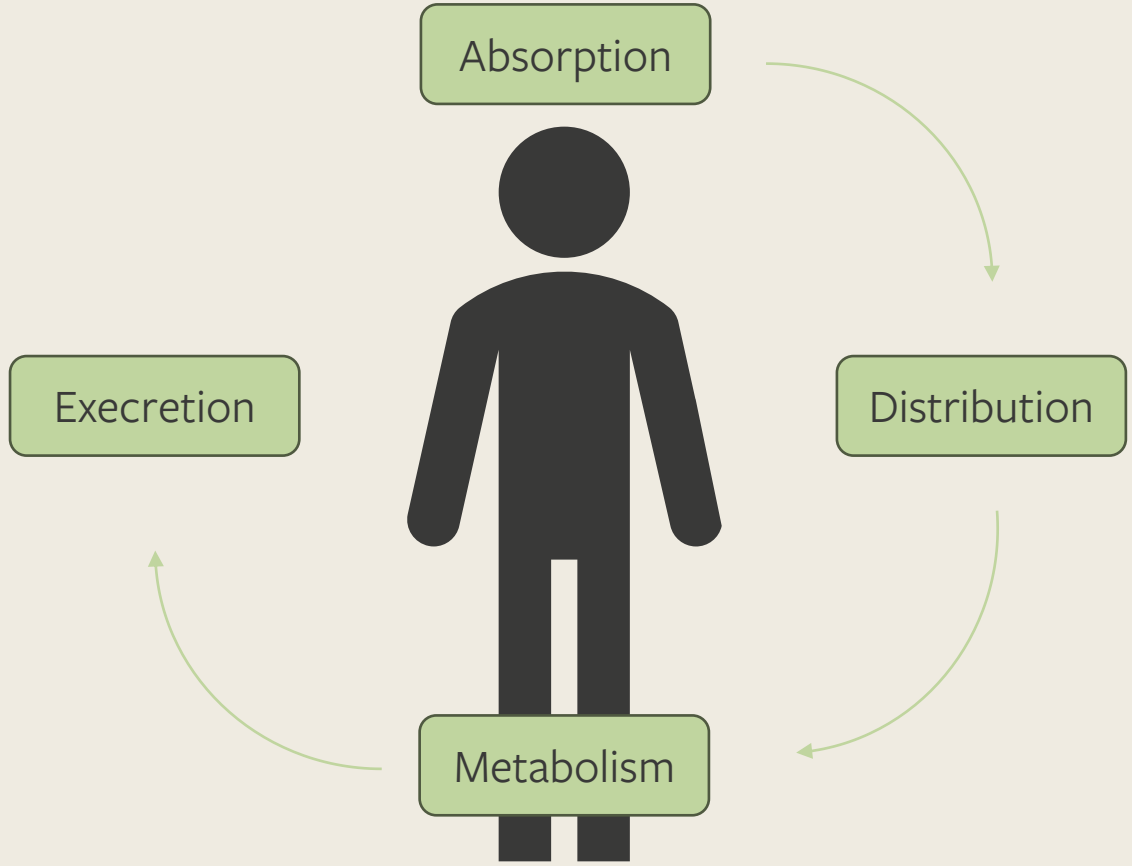
- Daily treatment for 14 days (day 28 – day 41)
- The combination of NOV202 with PARP inhibitors had a distinct synergistic effect.



Predicted Human Pharmacokinetics

Advanced in silico modelling predicts adequate human pharmacokinetic properties

- Good oral bioavailability (30 %)
- Moderate half-life (3 h)
- Good brain penetration
- Not a substrate for P-gp efflux pumps
- High permeability & good tissue binding
- Clearance not dependent on renal function



CMC

- Two steps synthesis with high yield and purity
  - ✓ Synthesis has been optimized and process developed for large scale production
  - ✓ The first technical batch gave 249 g of NOV202 with 81 % total yield and 99 % purity
- Low production costs
- Initial solid state analysis and stability studies have been performed as well as development of a formulation, both liquid and nanosuspension
- Over 200 compounds have been synthesized in these series in Noviga's substance library

Safety

Histology evaluation of major organs after seven days at therapeutic levels

- No observed toxicity of NOV202 in liver, kidney, spleen and GI tract at therapeutic dose
- No clear substance related effects on body weight observed

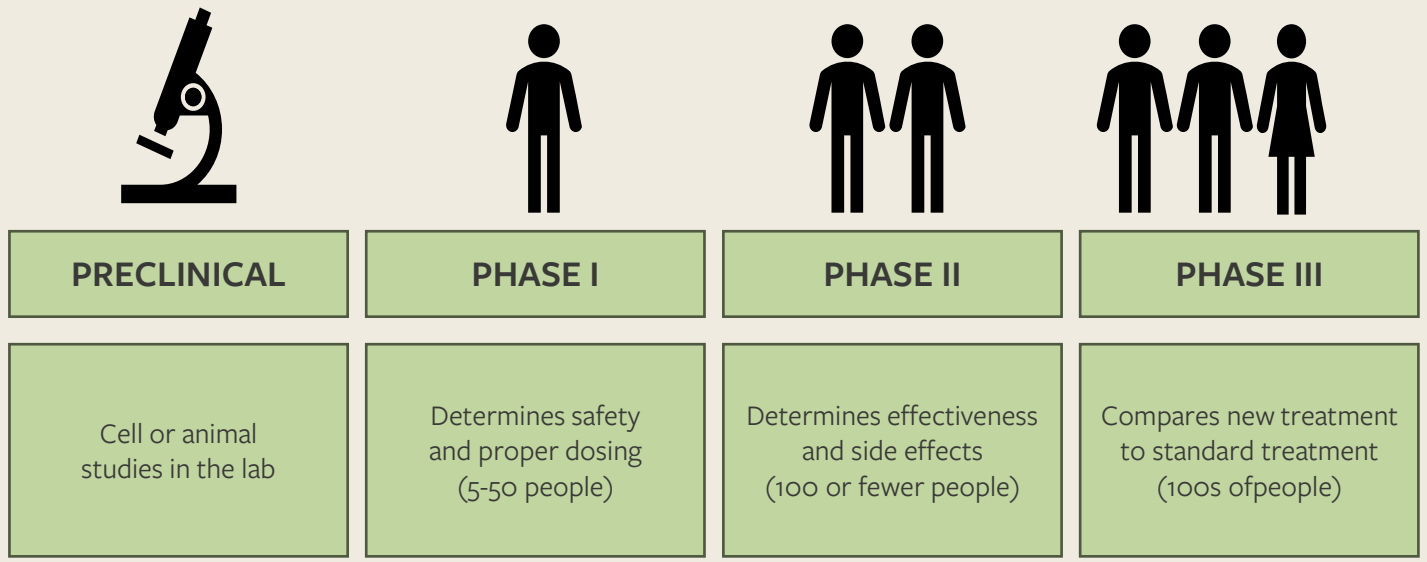
A 14-day, once-daily oral toxicology study was performed

- The dose used in the efficacy studies (30mg/kg) was judged to be tolerated well.
- No significant histological findings were observed, and no major findings were dose related.
- No findings in the study indicates a risk for major adverse toxicity effects by NOV202 at therapeutic doses.

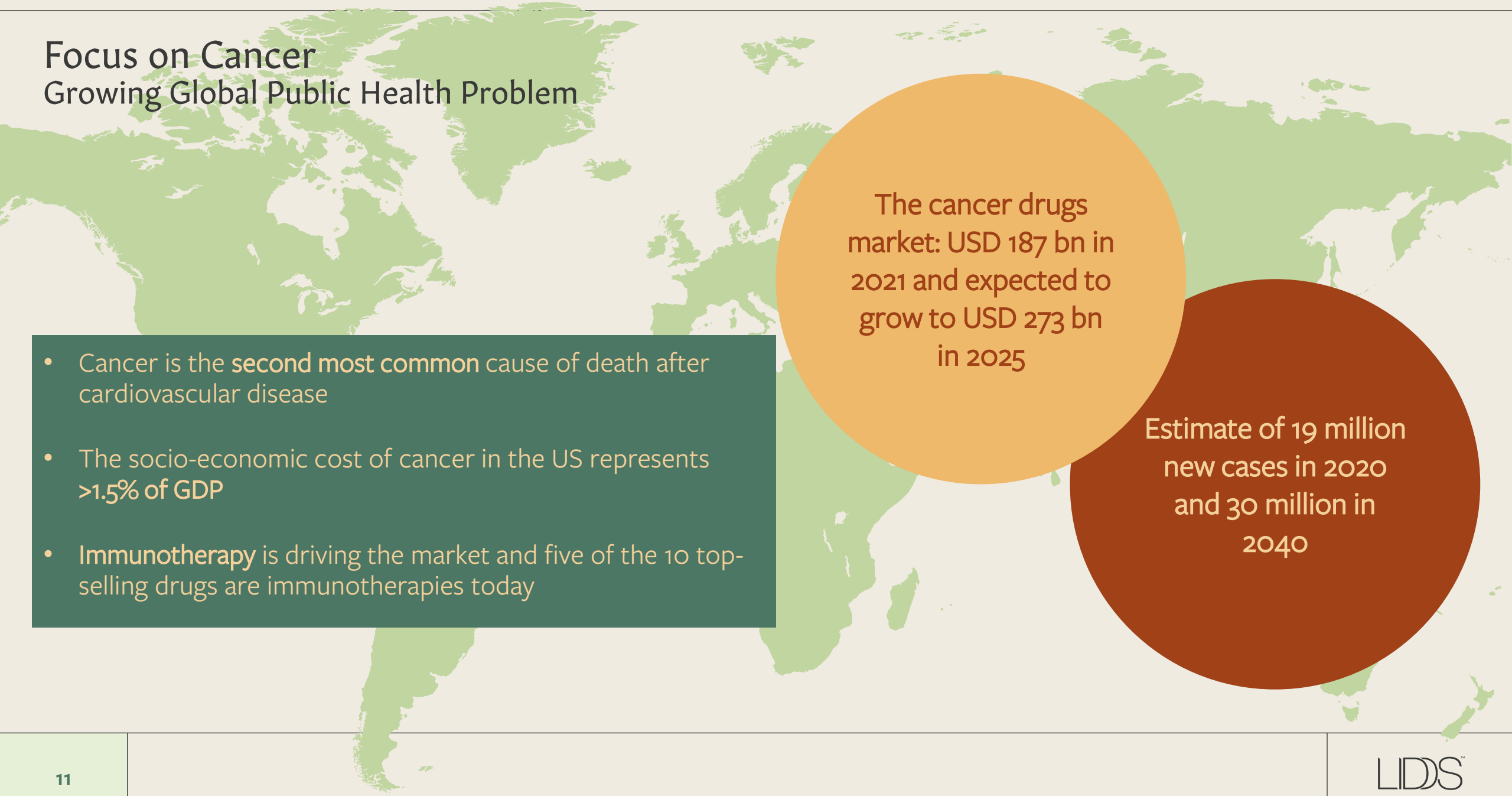
Next step a 28-day GLP toxicology study

Regulatory

- Advisory meeting with Swedish MPA
  - ✓ Support for IND-enabling safety studies in one species (mouse)
  - ✓ Confirmed preclinical package and plans
  - ✓ Support for clinical Phase I design



Focus on Cancer
Growing Global Public Health Problem



- Cancer is the **second most common** cause of death after cardiovascular disease
- The socio-economic cost of cancer in the US represents **>1.5% of GDP**
- **Immunotherapy** is driving the market and five of the 10 top-selling drugs are immunotherapies today

The cancer drugs market: USD 187 bn in 2021 and expected to grow to USD 273 bn in 2025

Estimate of 19 million new cases in 2020 and 30 million in 2040

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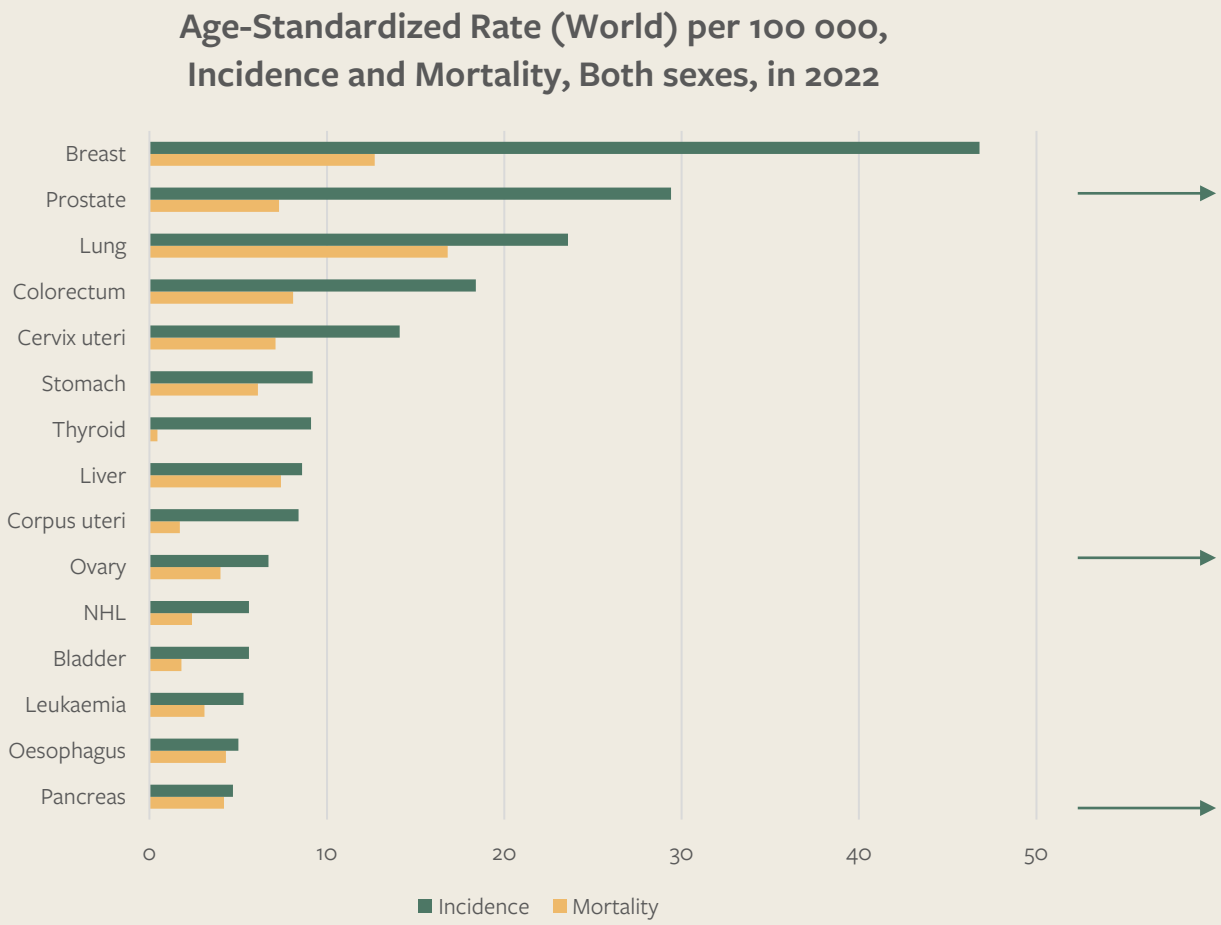
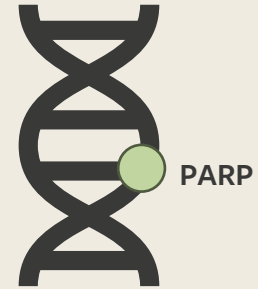
Cancer incidence



- NOV202 tested cancer models
  - ✓ Prostate cancer – very high incidence
  - ✓ Ovarian cancer – lower incidence, but still high mortality
  - ✓ Pancreas – very high mortality

PARP inhibitor Market

- PARP, or poly (ADP-ribose) polymerase, is an enzyme that helps repair DNA damage in cells. Unrepaired DNA prevents cells from dividing and multiplying, resulting in cell death. PARP inhibitors are drugs that block the DNA-repairing mechanism of PARP.
- PARP inhibitors are approved mainly for treating
  - ✓ Ovarian cancer
  - ✓ Breast cancer
  - ✓ Prostate cancer
  - ✓ Pancreatic cancer



- PARP inhibitors market was 3.1 billion USD in 2022, expected to increase to over 10 bUSD in 2031
- Largest drugs on the market
  - ✓ Olaparib (AstraZeneca)
  - ✓ Niraparib (Pfizer)
  - ✓ Talazoparib (Pfizer)
  - ✓ Rucaparib (Pharma&)
  - ✓ Veliparib (Abbvie)