



Interim report January – September 2021

October 28, 2021

Martin Welschhof, CEO

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SUMMARY INTERIM REPORT JANUARY – SEPTEMBER 2021

- 2nd clinical trial and supply agreement with Merck for BI-1808/pembrolizumab combo in Phase 2
- BI-1206/rituximab Phase 1 in NHL to be showcased at ASH (American Society of Hematology) Dec 11-14, 2021
- Early data mid-December 2021 for BI-1206/pembrolizumab Phase 1 in solid tumors
- BT-001 preclinical poster at SITC Nov 2021
- BI-1607 CTA on track for submission before year-end
- Prof. Eggermont new member of Scientific Advisory Board
- Emma Meurling new HR Director



BioInvent Q3

INTERIM REPORT JANUARY 1 - SEPTEMBER 30, 2021

BioInvent's CEO:

"The powerful combination of BioInvent's R&D and in-house manufacturing provides invaluable support to our clinical development and facilitates the execution of our current clinical portfolio. The integration of functions, on top of world leading science, makes it possible for us to develop novel treatments for patients suffering from serious diseases. The solid balance sheet and strong, loyal shareholders support us in achieving our goals," said Martin Welschof.

Events in the quarter	Financial information
Third quarter 2021	Third quarter 2021
<ul style="list-style-type: none">• (R) BioInvent announced a second clinical trial collaboration and supply agreement with Merck to evaluate BI-1808 in combination with Keytruda® (pembrolizumab) in patients with advanced solid tumors.• Emma Meurling joined BioInvent as Human Resource (HR) Director.	<ul style="list-style-type: none">• Net sales SEK 5.0 (16.3) million.• Loss after tax SEK -62.6 (-52.9) million.• Loss after tax per share before and after dilution SEK -1.07 (-1.00).• Cash flow from operating activities -57.5 (-51.4) million.
Events after the period	January – September 2021
<ul style="list-style-type: none">• BioInvent and Transgene announced that preclinical data for BT-001, a novel oncolytic virus delivering an anti-CTLA-4 antibody for the treatment of solid tumors, will be presented at SITC in November 2021.• New data on the lead drug candidate BI-1206 Phase 1/2a study in non-Hodgkin's lymphoma (NHL) to be presented at the ASH (American Society of Hematology) conference, December 11-14.• New production agreement with CRUK to produce additional batch of anti-HER3 antibody.• Prof. Eggermont new member of the BioInvent Scientific Advisory Board.	<ul style="list-style-type: none">• Net sales SEK 14.5 (48.6) million.• Loss after tax SEK -199.7 (-104.9) million.• Loss after tax per share before and after dilution SEK -3.79 (-4.00).• Cash flow from operating activities SEK -170.1 (-91.8) million.• Liquid funds and long-term investments as of September 30, 2021: SEK 1,445.3 (642.1) million.

(R) = Regulatory event
The information was submitted for publication, through the agency of the contact person set out on page 23, at 8:00 a.m. CEST on

2021 - STRONG PIPELINE WITH MULTIPLE VALUE DRIVERS

Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
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Target: FcyRIIB

BI-1206/rituximab	NHL (MCL, MZL, iFL)					
BI-1206/pembrolizumab	Solid tumors					
BI-1607	Solid tumors					

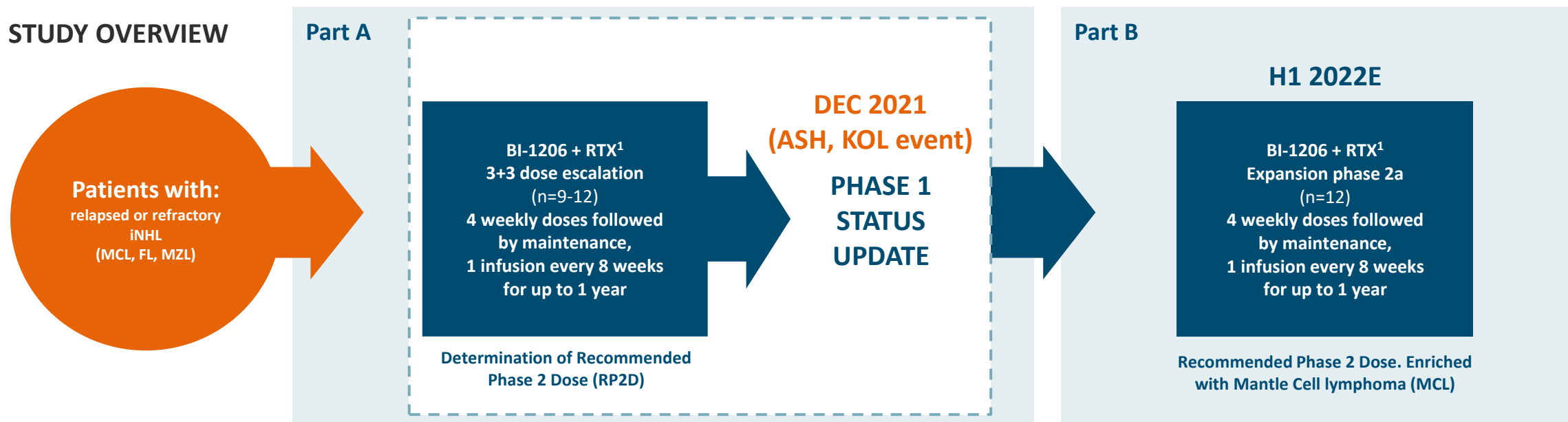
Target: TNFR2 and CTLA-4

BI-1808 (TNFR2)	Solid tumors					
BT-001 (CTLA-4, GM-CSF)	Solid tumors					
BI-1910 (TNFR2)	Solid tumors					

BI-1206 IN COMBINATION WITH RITUXIMAB: OPEN LABEL PHASE 1/2a STUDY

Ongoing phase

STUDY OVERVIEW



STUDY OBJECTIVES

- Explore safety & tolerability of the combination
- Select recommended phase 2 dose (RP2D)
- Determine pharmacokinetic and pharmacodynamic profile
- Observe early signs of efficacy
- Biomarker exploration (B cell depletion, depletion of circulating tumoral cells, analysis of biomarkers predictive of response)

INCLUSION CRITERIA

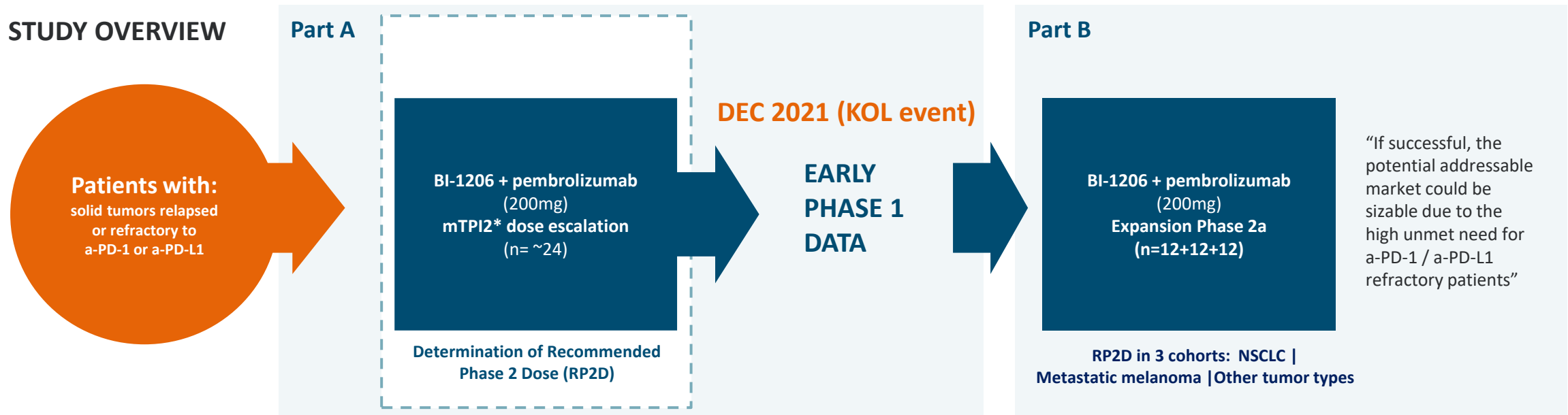
- Patients must have relapsed disease or disease that is refractory to conventional treatment or for which no standard therapy exists (R/R)
- Investigator judges available standard therapy as not being appropriate for the subject
- Occurrence of progressive disease after completion of a regimen of rituximab-containing therapy

BI-1206 IN COMBINATION WITH PEMBROLIZUMAB (SOLID TUMORS): PHASE 1/2a STUDY WITH MERCK

Ongoing phase



STUDY OVERVIEW



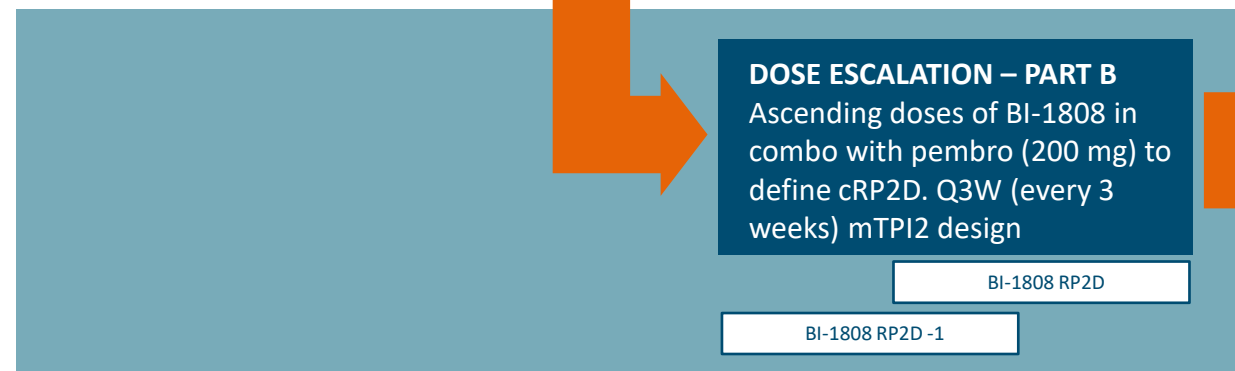
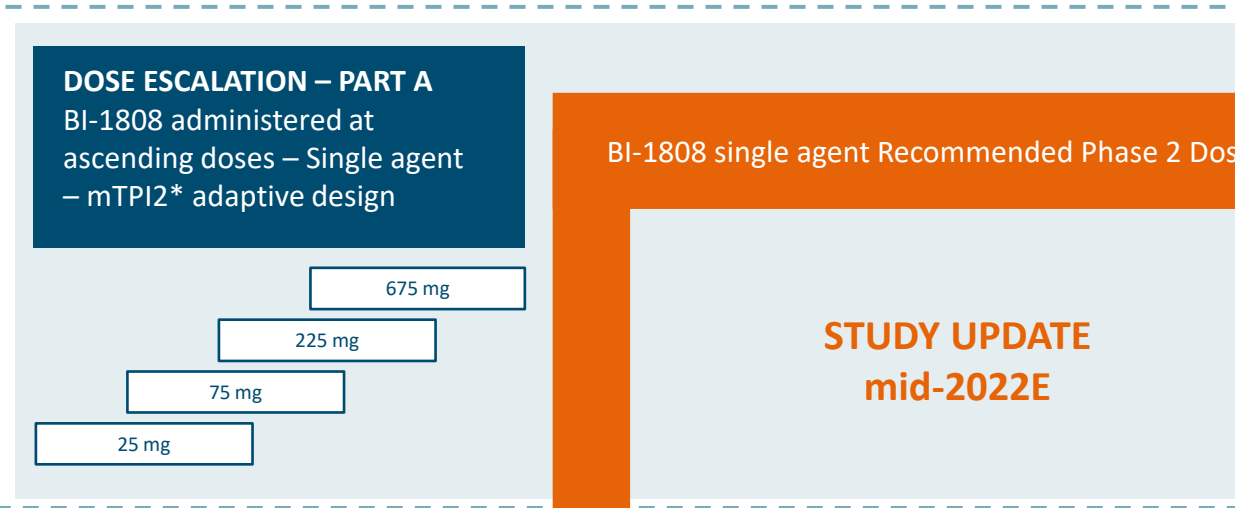
STUDY OBJECTIVES

- Confirm strong rationale for combination, as FcγRs have been shown to modulate the activity of immune checkpoint inhibitors
- Explore overexpression of FcγRIIb that may determine resistance to anti-PD-1 therapy in metastatic melanoma, NSCLC and others
- Explore safety & tolerability and illustrate pharmacokinetic and pharmacodynamic profile of combination
- Determine recommended Phase 2 dose (RP2D)
- Observe early signs of efficacy
- Biomarker exploration (B cell depletion, analysis of biomarkers predictive of response)

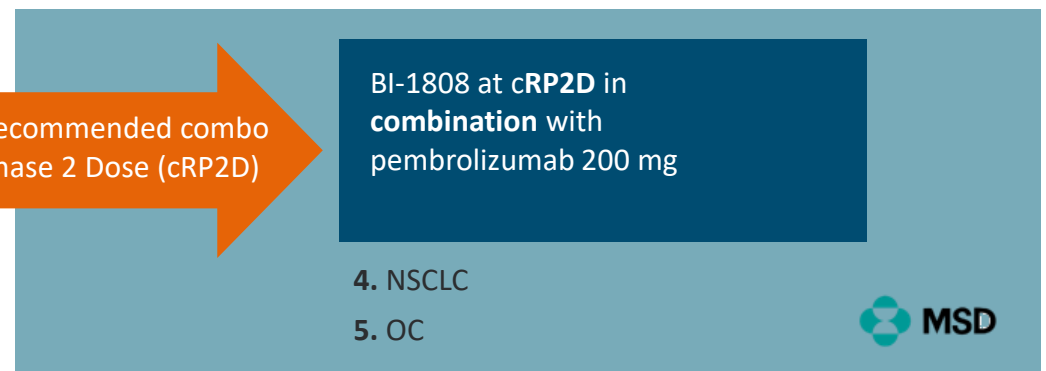
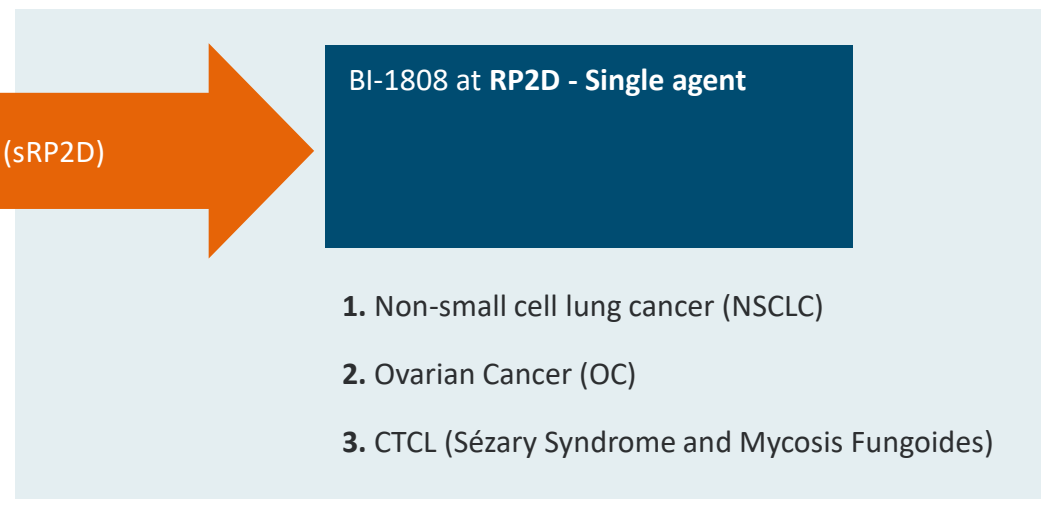
BI-1808 (ANTI-TNFR2): PHASE 1 ONGOING CLINICAL STUDY DESIGN

Ongoing phase

Phase 1: All Cancer Types



Phase 2a: Tissue-specific cohorts - 12 patients each



BI-1808 single agent Recommended Phase 2 Dose (sRP2D)

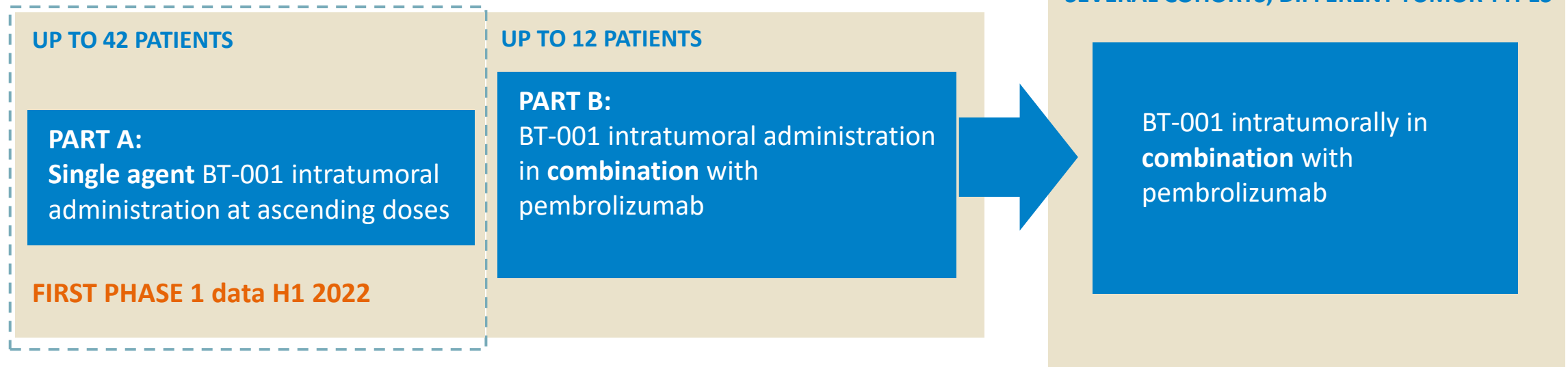
**STUDY UPDATE
mid-2022E**

Recommended combo
Phase 2 Dose (cRP2D)



BT-001 (VV_{cop}TK-RR⁻, ANTI-CTLA-4, GM-CSF): ONGOING PHASE 1/2A OPEN-LABEL, MULTICENTER, DOSE-ESCALATION STUDY

PHASE 1 - PART A & B



Ongoing phase

FINANCIAL OVERVIEW

SEK million	Q3 2021	Q3 2020	Jan.-Sep. 2021	Jan.-Sep. 2020
Net sales	3,0	16,3	14,5	48,6
<i>Operating costs</i>				
Research and development	-57,6	-41,3	-187,9	-131,3
Sales and administrative costs	-7,8	-7,5	-27,5	-22,7
Other operating revenue and costs	0,0	-0,3	1,4	0,5
	-65,4	-49,1	-214,0	-153,5
Operating profit/loss	-62,4	-32,8	-199,5	-104,9
Loss from financial investments	-0,2	-0,1	-0,2	0,0
Profit/loss for the period	-62,6	-32,9	-199,7	-104,9
Cash flow from operating activities	-57,5	-31,4	-170,1	-91,8
Liquid funds and long-term investments at end of period	1 445,3	642,1	1 445,3	642,1

- **Net sales January - September 2021 include:**

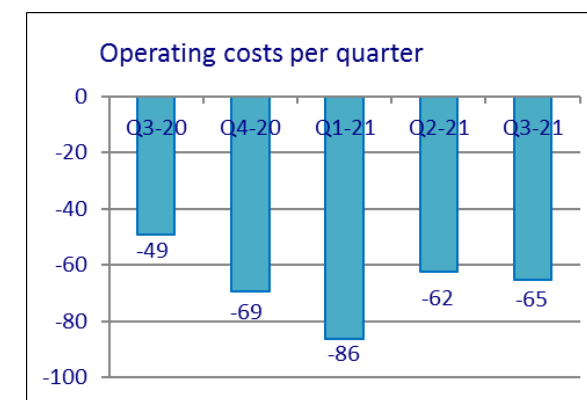
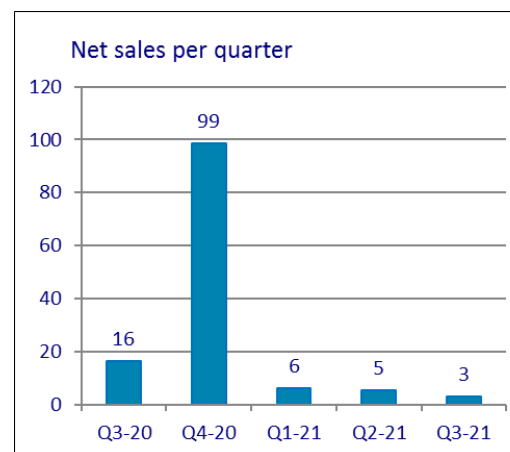
- Revenues from production of antibodies for clinical studies.

- **Operating costs January - September 2021 include:**

- A one-time payment of GBP 2.5 million (SEK 28.4 million), when BioInvent restructured a clinical development agreement with Cancer Research UK (CRUK) for BI-1206. In exchange was Bioinvent's obligations to CRUK reduced.

- **Financing activities in 2021:**

- The share issue completed in March 2021 amounted to in total SEK 962 million before issue expenses.



WHAT TO LOOK OUT FOR 2021

- **BI-1206/rituximab** in NHL – Phase 1 update at ASH Annual meeting Dec 11-14, 2021
- **BI-1206/pembrolizumab** in solid tumors – Early Phase 1 data Mid-Dec 2021
- **BI-1206** BioInvent KOL event Mid-Dec 2021
- **BI-1206** China IND Q4 2021E
- **BI-1607** CTA submission End of year 2021E

October 2021





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