



**OTCQB: CYTR** 

# Corporate Overview August 2021

**Non-Confidential** 

## **CytRx Safe Harbor Statement**

THIS PRESENTATION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE CERTAIN RISKS AND UNCERTAINTIES. ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF VARIOUS RISKS AND UNCERTAINTIES, INCLUDING THOSE RISK FACTORS DISCUSSED IN THE ANNUAL AND QUARTERLY REPORTS THAT CYTRX FILES WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION.



## **CytRx Highlights**

- CytRx's milestone and royalty agreement with Orphazyme for arimoclomol could represent potential near term payments to CytRx
- Orphazyme has submitted a Marketing Authorisation Application with EMEA authorities for arimoclomol for NPC
- ImmunityBio has initiated a Phase 2 registrational-intent study for first-line and second-line locally advanced or metastatic pancreatic cancer, which includes aldoxorubicin and expects to release survival data in Q1/22 for Cohort C
- Centurion BioPharma is a private oncology drug development company focused on cancer and has completed extensive pre-clinical work for its ultra high potency LADR™ drug candidates and albumin companion diagnostic (ACDx)



# CytRx has potential milestone/royalty payments and a subsidiary called Centurion BioPharma

Orphazyme Milestones and Royalties

Orphazyme: Potential Milestones plus royalties on arimoclomol

ImmunityBio Milestones and Royalties

ImmunityBio: \$343M in potential milestones; plus royalties on aldoxorubicin

Centurion BioPharma Pipeline

Oncology drug development with a companion diagnostic

Centurion BioPharma is a wholly-owned subsidiary of CytRx



### CytRx milestones and royalties from Orphazyme for Arimoclomol

Orphazyme Milestones and Royalties

Orphazyme: Potential milestones in addition to royalties on arimoclomol

### Niemann-Pick disease ("NPC")

- Orphazyme submitted an MAA with the EMA for arimoclomol for NPC, with European regulatory CHMP opinion expected in Q4/21
- Orphazyme filed an NDA with the FDA with Priority Review and received a Complete Response Letter on June 17, 2021; they will be working with the regulators to find a possible path forward.
- Orphazyme launched an Early Access Program for NPC in January 2020 to further accelerate access to treatment with arimoclomol for people living with NPC.
- Total worldwide patients approximately 3,000.
- Expected price range is \$300,000 \$600,000; EU market potential \$300 Million.
- Go to market in EU/RoW H1 2022.





### WHAT IS NPC? Niemann-Pick Disease Type C

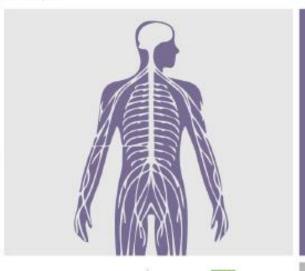
#### NPC IS A RARE, INHERITED, PROGRESSIVE, AND OFTEN FATAL NEURODEGENERATIVE DISEASE

NPC is a lysosomal storage disorder caused by genetic mutations that often lead to misfolded variants of NPC proteins. Misfolded NPC protein does not function properly and is subject to rapid degradation.



1-2000

people are diagnosed with NPC in the USA and EU





#### MANIFESTATIONS

The disease affects the brain, liver, succumb to the disease before reaching the end of their teens.

patients gradually loses:

Motor function and coordination

Memory



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95% have mutations in the NPC1 gene have mutations



is currently approved to treat NPC (Zavesca).



#### DIAGNOSIS

Difficult to diagnose, NPC is often diagnosed by ruling out other diseases, which may take years.

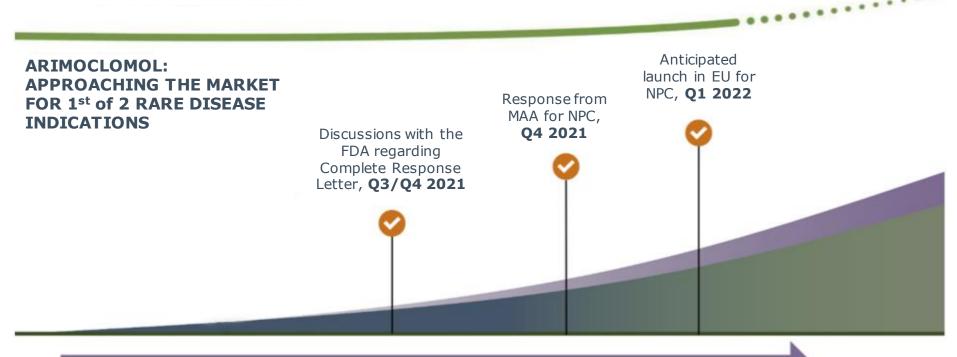
There is **NO CURE** for NPC



Source: www.orphazyme.com

## Orphazyme preparing for commercialization in 2022 for arimoclomol

Orphazyme: Preparing for commercialization in 2022



Building a highly specialized commercial footprint in US and EU



Source: www.orphazyme.com

## CytRx potential milestones and royalties from ImmunityBio for aldoxorubicin

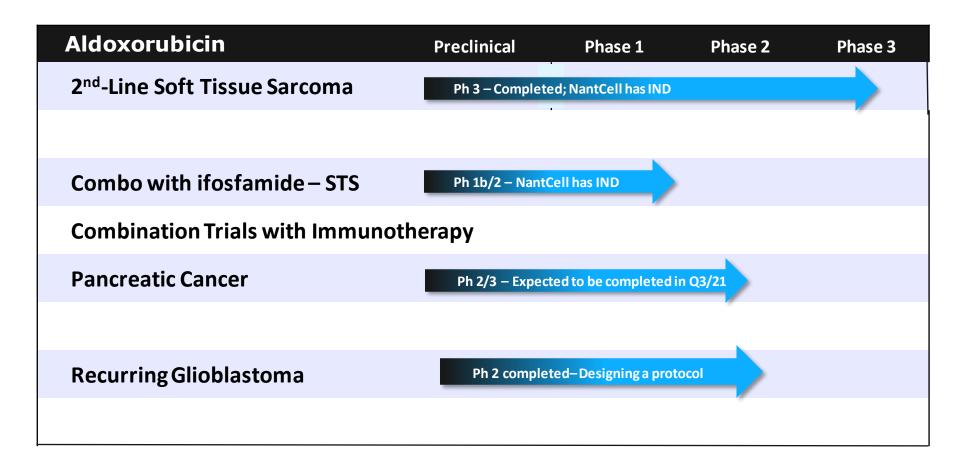
ImmunityBio Milestones and Royalties

ImmunityBio: up to \$343M in milestones In addition to royalties on aldoxorubicin

- ImmunityBio has merged with NantKwest and trades under IBRX
- ImmunityBio has highlighted aldoxorubicin as one of three separate modalities of its platform.
- ImmunityBio announced initiation of a phase 2 registrational-intent study using aldoxorubicin in combination with immunotherapy in metastatic pancreatic cancer, which they expect to be completed in the third quarter of 2021. An early readout of survival data for Cohort C is expected in the first quarter of 2022.
- ImmunityBio, to date, plans to use aldoxorubicin in studies in glioblastoma, in addition to metastatic pancreatic cancer.
- CytRx is entitled to increasing double-digit royalties on aldoxorubicin for soft tissue sarcomas and increasing single-digit royalties for all other indications
- ImmunityBio is reviewing options in Soft Tissue Sarcoma.



## CytRx partnered Pipeline with ImmunityBio - aldoxorubicin





## Update from NantKwest/ImmunityBio at JP Morgan Conference in January 2021

## Metastatic Pancreatic Cancer QUILT-88: early indications of increased survival rate with no other approved treatment options

- In initial QUILT trials, median overall survival rate more than doubled compared to historical controls
- A single-arm Phase 2 trial was initiated in October 2020, for which the primary endpoint is overall survival and 83% of patients enrolled with second-line or greater pancreatic cancer remain alive to date
- Former Senate Majority Leader Harry Reid's stage IV pancreatic cancer is now in "complete remission" after receiving this experimental combination immunotherapy that included aldoxorubicin
- Initiation of a <u>Registrational-Intent</u> Phase 2 randomized, three-cohort, open-label study for first and second-line treatment of locally advanced or metastatic pancreatic cancer
- Randomized trials in first and second-line pancreatic cancer are actively recruiting at three sites with more than 50 patients enrolled or being evaluated in QUILT-88 to date



### CytRx subsidiary Centurion BioPharma has an oncology preclinical pipeline and diagnostic

Centurion BioPharma Pipeline

Oncology drug development with a companion diagnostic

## LADR™ (linker activated drug release) <u>albumin</u> binding drug conjugates

LADR-7 (auristatin)

LADR-8 (auristatin)

LADR-9 (maytansinoid)

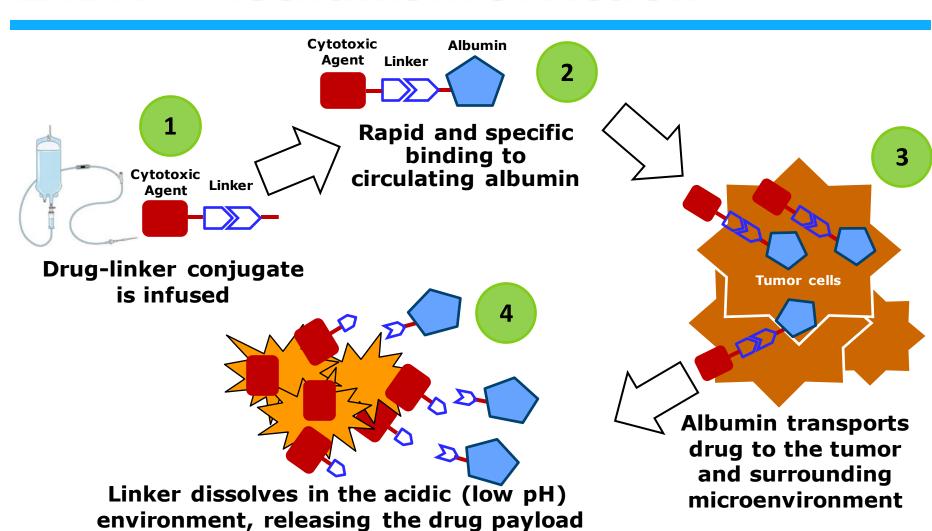
LADR-10 (maytansinoid)

### **Albumin** companion diagnostic (ACDx)

identifies tumors eligible for treatment with LADR™



### **LADR™** Mechanism of Action





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## Recent and Upcoming Catalysts

#### 2020-2021

- √2H 2020: Orphazyme has submitted for EMEA (Europe) approval for arimoclomol in Niemann-Pick Type C ("NPC") disease
- √Q4 2021: Orphazyme expecting European regulatory CHMP opinion for arimoclomol in NPC
- Q1 2022: Upon approval, CytRx is to receive a \$6 million milestone payment if Europe and Japan are approved (\$4 million for Europe and \$2 million for Japan)
- Q1 2022: ImmunityBio expecting read out of survival data for Cohort C on the metastatic pancreatic cancer trial



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## **Financial Summary**

Cash Position – pro-forma (07/31/21)

\$18.6M

No Debt

Shares Outstanding - common

38.8M

preferred 8,240

Convertible into 9.3 M common

Options Weighted-average strike price: \$8.15
2.9M

Fully-Diluted Share Count - pro-forma (7/31/2021)41.7M

Pro-forma including conversion of preferred 51.0 M



### **Summary**

- Orphazyme could deliver milestones and royalties
- ImmunityBio could deliver milestones and royalties
- Cash burn rate is ~\$377k per month
- Potential to shelter future income with non-restrictive net-operating carry-forward losses ("NOL's") of \$258 million

