

Specialists in
Developing and Commercializing
Infectious Disease Medicines

**CORPORATE PRESENTATION – JANUARY 22, 2024** 



## **DISCLAIMER & FORWARD-LOOKING STATEMENTS**

DISCLAIMER. The information contained herein has been prepared to assist prospective investors in making their own evaluation of 60 Degrees Pharmaceuticals, Inc. (the "Company") and does not purport to be all-inclusive or to contain all of the information a prospective or existing investor may desire. In all cases, interested parties will be expected to have conducted their own due diligence investigation regarding these and all other matters pertinent to investment in the Company. The Company makes no representation or warrant as to the accuracy or completeness of this information and shall not have any liability for any representations (expressed or implied) regarding information contained in, or for any omissions from, this information or any other written or oral communications transmitted to the recipient in the course of its evaluation of the Company. This presentation and contents herein are the exclusive property of the Company and may not be copied without the express prior written consent of the Company.

**FORWARD LOOKING STATEMENTS.** This communication includes forward-looking statements based on the Company's current expectations and projections about future events. All statements contained in this communication other than statements of historical fact, including any statements regarding our future operations, are forward-looking statements. The words "believe", "may", "will", "estimate", "continue", "anticipate", "intend", "expect", "could", "would", "project", "plan", "potentially", "likely" and similar expressions are intended to identify forward-looking statements as defined in the Private securities Litigation Reform Act of 1995.

The forward-looking statements contained in this communication are based on knowledge of the environment in which the Company currently operates and are subject to changed based on various important factors that may affect the Company's operations, growth strategies, financial results and cash flows, and as well as other factors beyond the Company's control as of the date of this presentation.

Important factors that could cause our actual results and financial conditions to differ materially from those indicated in the forward-looking statements include, among others, the following: there is substantial doubt as to our ability to continue on a going-concern basis; we might not be eligible for Australian government research and development tax rebates; if we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for Tafenoquine (Arakoda or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations; we cannot guarantee our ability to conducted successful clinical trials; and we have no manufacturing capacity which pits at risk of lengthy and costly delays of bringing our products to market. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-k and our subsequent Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. As a result of these matters, changes in fact, assumptions not being realized or other circumstances, the Company's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this presentation.

In light of these risks, uncertainties and assumptions, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Although we believe our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Unless required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.



## Overview

60 Degrees Pharmaceuticals, a growth-oriented biotech company, specializes in the development and commercialization of new therapies used to treat and prevent serious infectious diseases.

Cutting-edge biological science and applied research form the foundation of our highly-focused, advanced clinical strategy.

In 2019, 60P's malaria prevention product, ARAKODA® (tafenoquine), was made commercially available after receipt of U.S. regulatory approval in 2018.

Our current product development targets include tickborne, viral, fungal and other serious infectious diseases with unmet needs we perceive in the marketplace.





# About ARAKODA® [tafenoquine succinate]

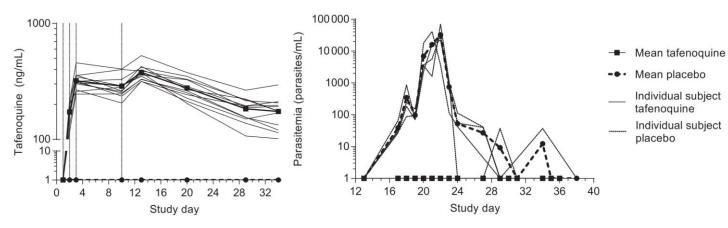
- Developed by US Army as a prophylactic antimalarial (through 2013)
- 60P and USAMMDA formed a partnership in 2014:
  - FDA approval in 2018 [for malaria prevention]
  - Commercially available in U.S. from Q3 2019
- Dosing & Duration of Use
  - Load: 200 mg/day x 3 days
  - Maintenance: 200 mg once per week
- Safety Profile
  - 8 published clinical studies involving > 1,100 patients
  - Overall adverse event rate of tafenoquine 200 mg weekly for 52 weeks is comparable to placebo.
  - G6PD screening required prior to use
  - See paper in Travel Medicine & Infectious Disease [Long-term safety of the tafenoquine antimalarial chemoprophylaxis regimen: A 12-month, randomized, double-blind, placebo-controlled trial ScienceDirect]

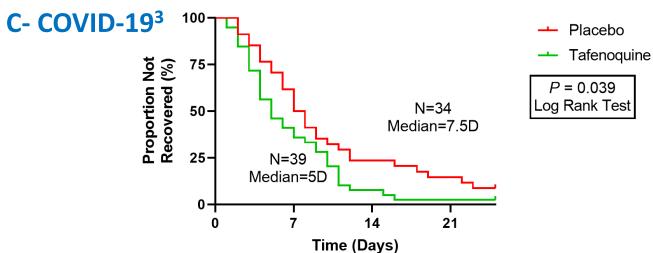




# Tafenoquine – Potential Use in Multiple Indications

#### A – Malaria<sup>1</sup>

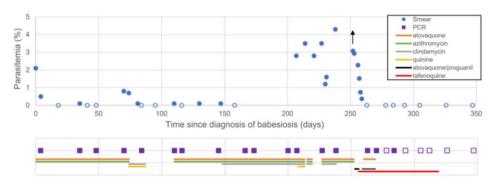




### B – Yeasts & Fungi<sup>2</sup>

	Tafenoquine MIC [ug/mL]		
Species/Strain	50% inhibition	Complete suppression	Fluconazole MIC [ug/mL]
Candida parapsilosis ATC 22019	4	4	ı
C. crucei ATCC 6258	4	4	32
C. albicans SC5314	8	8	0.5
C. albicans ATC 90028	4	4	0.25
C. albicans CA3	4	4	> 64
C. auris D117-47	4	4	> 64
C. auris D117-48	2 4	4	2
C. auris D117-46		4	> 64
C. glabrata 05-62	8	8	> 64
C. glabrata 05-761	8	8	8
C. glabrata CG3	8 2 2 4	8 4 2 4	32
C. guilliermondii Cgui I	2	4	1
C. guilliermondii Cgui2	2	2	2 2
C. guilliermondii Cgui3			
C. parapsilosis CPI	4	4	0.5
C. parapsilosis CP2	4	4	0.5
C. parapsilosis CP2	4	8	0.5
Cryptococcus neoformans USC1597	4	4	4
C. neoformans H99	4	4	16
C. neoformans CN3	4	4	64
Average (SD)	4.5 (1.9)	4.9 (1.9)	NC

#### D – Babesiosis<sup>4</sup>



1. McCarthy et al. CID 2019;69:480-486. 2. Dow & Smith. New Microbes New Infections; doi: 10.1016/j.nmni.2022.100964. 3.. Unpublished data from NCT0453347. 4. Rogers et al CID 2022; doi: 10.1093/cid/ciac473.



## **About Babesiosis\***

- Tick-borne disease caused by protozoan parasites of the genus Babesia
- Invades red blood cells causing:
  - Non-specific flu-like symptoms, anemia
  - Potential severe complications
  - Death (1.6% mortality rate in hospitalized patients/10% in those with cardiac complications)
  - May be refractory to treatment in immunosuppressed patients
  - Associated with chronic post-treatment syndrome
- Common in Mid-West and North-Eastern U.S.
  - Geographic range expanding and incidence increasing
- Common coinfection with Lyme disease (10% of cases)



Babesiosis







# Babesiosis Patient Volume and Standard of Care (First Cut)

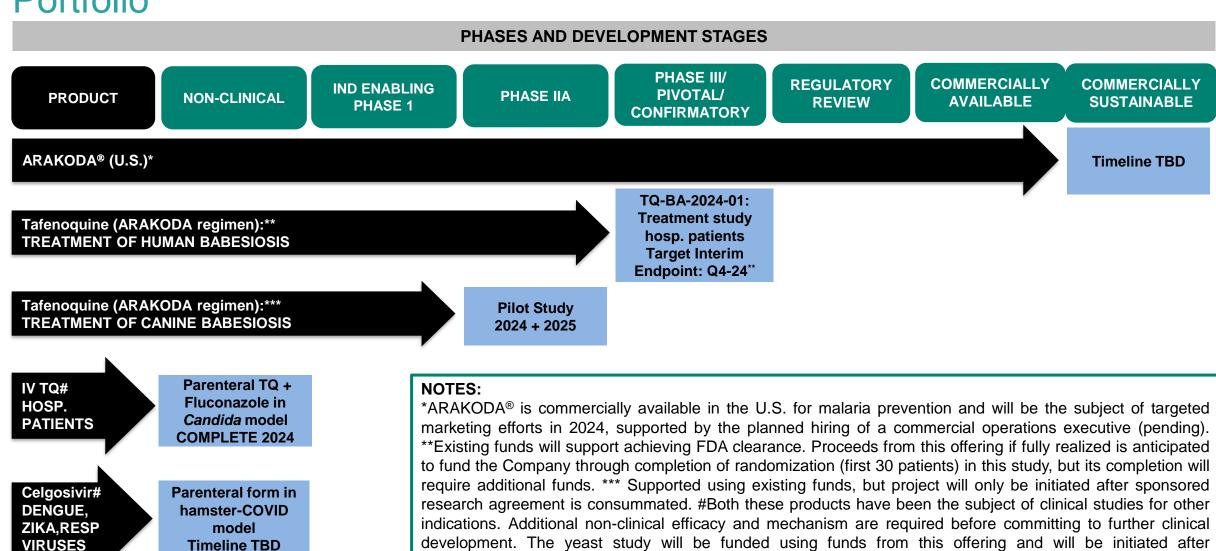
- At risk populations are potentially large but poorly defined in medical literature
- Standard of care treatment regimens for babesiosis are long, complicated, or don't exist

Potential Indications	Potential Patient/Prescription Volume	Existing Standard of Care
Babesiosis – Treatment Immunosuppressed Hospitalized Outpatient	< 1,400* Up to 1,400* Up to 38,000*	First Line: Azithromycin + atovaquone for ~10 days or > 6 weeks if immunosuppressed**
Babesiosis – Prevention Post Exposure (tick bites) Pre-Exposure	Up to 400,000*** Up to 1.2 million #	Insect repellents, protective clothing
Chronic Tick-Borne Diseases Babesiosis PTLDS (new/cumulative through 2020)	Unknown Up to 95,000/1,9000,000&	No specific FDA-approved treatments

<sup>\*</sup> Total babesiosis patients in U.S. may be approximately 47,000 per year based on the observation that there are 476,000 lyme infections each year, 10% of which are also babesiosis coinfections (Krause et al JAMA 1996;275:1657-16602. Krugeler et al *Emerg Infect Dis* 2021;27:616-61). Approximately 80% of adult babesiosis infections are symptomatic, yielding a treatable patient pool of about 38,000. There are up to 1,400 hospitalized cases per year in the U.S (Bloch et al 2022 Nov 8;9(11):ofac597. doi: 10.1093/ofid/ofac597. eCollection 2022 Nov.), an unknown (i.e. < 1,400) number of of which represent immunosuppressed patients. \*\* According to IDSA guidelines.\*\*\* Based on the observation that 50,000 tick bites are treated in US emergency rooms each year, representing about 12% of the total number (Marx et. al., MMWR 2021;70:612-616) # Determined on a pro rata basis using company estimates of malaria market as being 550,000 three-week prescription per year amongst an at-risk travel population of ~ 8.5 million, versus a seasonally adjusted at-risk population for *B. microti* infection in the U.S. of ~ 17.5 million. \*Cumulative incidence in U.S. in 2020. Delong et al. 2019 Apr 24;19(1):352. doi: 10.1186/s12889-019-6681-9.



### Portfolio





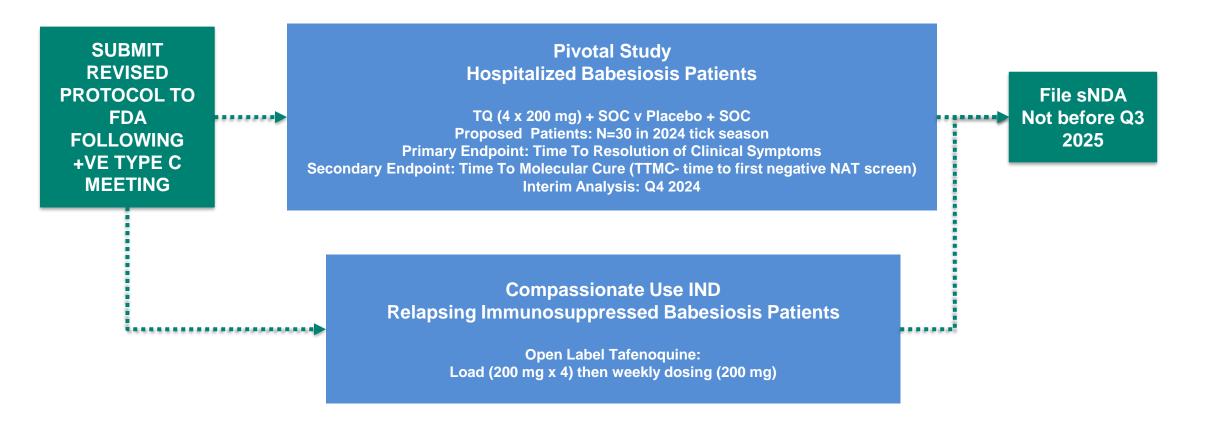
= Completed

= Next phase

share sales by a partner organization in the future (timeline TBD).

consummation of a sponsored research agreement. The celgosivir project will be funded from proceeds of 60P

## Babesiosis Clinical Development Plan (Proposal for FDA)





## Commercial Infrastructure & Supply Chain

**API & Tablets** 



Piramal, India

**Packaging** 



PCI, Philadelphia, U.S.

**3PL Title Model** 



ICS, Brooks KY, USA

**Distributors** 



ASB, Two Other U.S. Prime Vendors



**PBMs** 

**Various** 

## Intellectual Property & Licensing

#### 60 Degrees Pharmaceuticals has freedom to operate

#### ■ U.S. Arakoda Patents (2 issued/6 in progress)

- Tafenoquine for malaria prevention patent family: Earliest expiration <u>December 2034</u>
- Tafenoquine for lung Infections/COVID Treatment: Earliest expiration March 2041

#### U.S. Celgosivir Patents

- Dengue/RSV (4 issued/2 in progress)
- COVID-19 licensed from FSU (1 issued/1 in progress)

#### International Patents

6/2 for Celgosivir issued/in progress, 1/8 for tafenoquine issued/in progress

#### Clinical, non-clinical and manufacturing information:

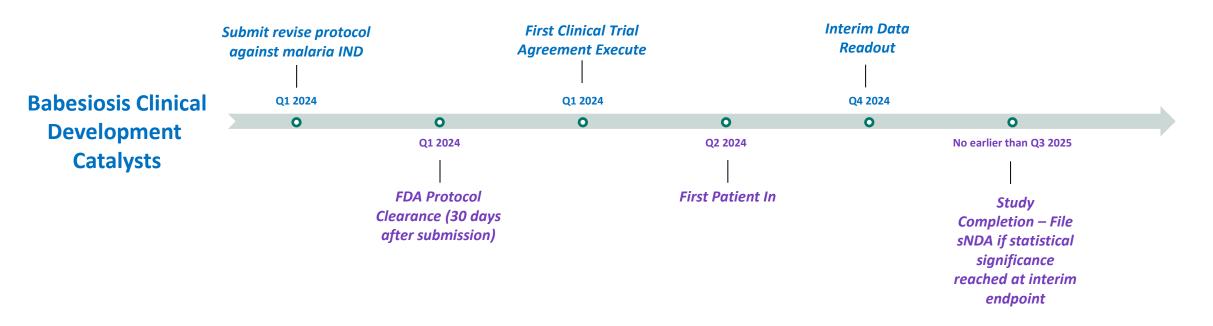
Worldwide rights for all indications [except P. vivax malaria] licensed from US Army

# Existing License & Distribution Agreements [Malaria]

Territory	Partner
Europe	Scandinavian Biopharma
Australia, NZ, Pacific Islands	Biocelect
Canada, Latin America, Israel, Russia	Knight Therapeutics



# Anticipated Future Milestones (Pivotal Babesiosis Study)



#### **OTHER ANTICIPATED MILESTONES**

- Hiring of Chief Commercial Officer
- TAM estimates for tick-borne diseases

- Trade & scientific conferences
- New product development collaborations



## Officers & Directors



#### **Geoffrey Dow MBA PHD, CEO & Chairman**

- Affiliations: WRAIR, USAMMDA
- Founded & led 60P from 2010-2023
- Industry Project Leader on Arakoda NDA



Ty Miller, CFO

- CPA
- CFO since 2014
- Over 20 years in Private Practice



#### **Bryan Smith MD, Chief Medical Officer**

- Retired US Army Colonel/30+ years experience
- Two successful NDAs as a Chief Medical Officer
- Medical affairs/regulatory expert in GxP environment



#### Jenny Herz, Director of 60P Australia since 2013

- 20 years commercial experience in pharma (Sanofi, AZ)
- International launch experience with multiple products
- Co-founder of Biointelect and Biocelect
- Board experience in public, private, NFP sectors



#### **Cheryl Xu, Director**

- First PhRMA representative to China
- Senior Advisor to multinationals (market access and expansion)
- Project Leader (multiple public health projects)



#### **Stephen Toovey MD, PHD Director**

- Affiliations: Roche, Pegasus Research, WHO
   Collaborating Centre for Vaccines and Travel Medicine,
   London, UK
- Tropical medicine subject matter expert
- Respiratory virus subject matter expert



#### Paul Field, Director

- Affiliations: GARDP, Imunexus, Marinova
- 30 years global biotech business development experience
- Previously investment specialist at Austrade, focused on tropical medicine and NTDs



#### **Charles Allen, Director**

- Affiliations: BTCS & GBV
- CEO & Chairman of NASDAQ listed company
- Managing Director, several boutique investment banks
- Broad business experience across multiple sectors



## Investment Highlights

- ARAKODA a long-acting, potentially broad-spectrum, anti-infective already FDA-approved for malaria prevention and commercially available in the U.S.
  - Safe, long acting, mechanistically differentiated antimalarial approved by FDA
  - Discovered by US Army and successfully brought to market by 60P
  - 1,100+ patient exposures in 8+ published clinical trials, weekly dosing for up to one year
  - Commercially available in U.S. via network of major national distributors
  - Existing commercial/regulatory infrastructure expected to facilitate cost-effective pathway to new/expanded indications following targeted clinical trial and label changes
- Arakoda Regimen of Tafenoquine Research agenda involving babesiosis and other diseases
  - Malaria, COVID-19, fungal, tick-borne illness of interest to the Company affect millions and are associated with a potentially high revenue unmet medical need
  - Company has strong IP for malaria, COVID-19, and other indications
  - Accelerated clinical recovery from babesiosis is suggested by case studies of immunosuppressed patients administered tafenoquine
  - 2024 (+ 2025 if needed): Execute pivotal treatment study in hospitalized babesiosis patients
  - Q3 2025+: sNDA if/when appropriate
- Experienced management team and Board
  - Team has together led/managed four clinical trials
  - Collectively led multiple pharmaceutical product approvals/product launches
  - Collectively led/provided guidance on 20+ public & private entities
  - Participated in/led multiple public listings





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