ABVC BIOPHARMA

# Corporate Overview

**NASDAQ: ABVC**

**2023**

# Forward Looking Statements

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# ABVC BioPharma Highlights

## Cash-Efficient Development

*We partner with World-Class Research Institutions to in-license promising compounds and devices that have completed preclinical and Phase I or Phase II studies*

## 2023 Clinical Catalysts

| | |
|---|---|
| **Vitargus** | *Phase II expected to be completed by 1H 2024* |
| **ABV-1504** | *Completed Phase IIb in Q1 2023; initiating end of Phase II meeting with the FDA* |
| **ABV-1505** | *Phase IIb expected to be completed by the end of 2023* |

## Robust & Diverse Therapeutic Pipeline

*Advancing a pipeline of medical devices in ophthalmology & botanical-based therapeutics for psychiatric disorders and various cancers*

## Addressing Large Patient Populations & Markets

*Addressing over 20 million patients across multiple indications representing over $20B in market opportunities*

# ABVC BioPharma Business Model

## Discovery

- ✓ Identify promising drugs or medical devices that have successfully completed preclinical studies and/or Phase I safety studies at world-renowned research institutions
- ✓ In-license compounds and devices of interest to further develop

## Translation

- ✓ Conduct Phase I and Phase II clinical studies to demonstrate safety and efficacy profiles

## Commercialization

- ✓ Upon successful completion of Phase II trials, ABVC seeks to out-license or sell the asset to a large pharmaceutical company
- ✓ Earn royalties from licensing transactions

***Our Clinical Study Partners:***

UCSF University of California San Francisco

Stanford University

CEDARS-SINAI

Sydney Hospital & Sydney Eye Hospital

Memorial Sloan Kettering Cancer Center

# Leadership Team

## Management

**Howard Doong, MD, PhD**
Chief Executive Officer

**Chi-Hsin Richard King, PhD**
Chief Scientific Officer

**Leeds Chow**
Chief Financial Officer

**T. S. Jiang, PhD**
Chief Strategy Officer

## Scientific Advisory Board

**Yih-Shiou Hwang, MD, PhD**

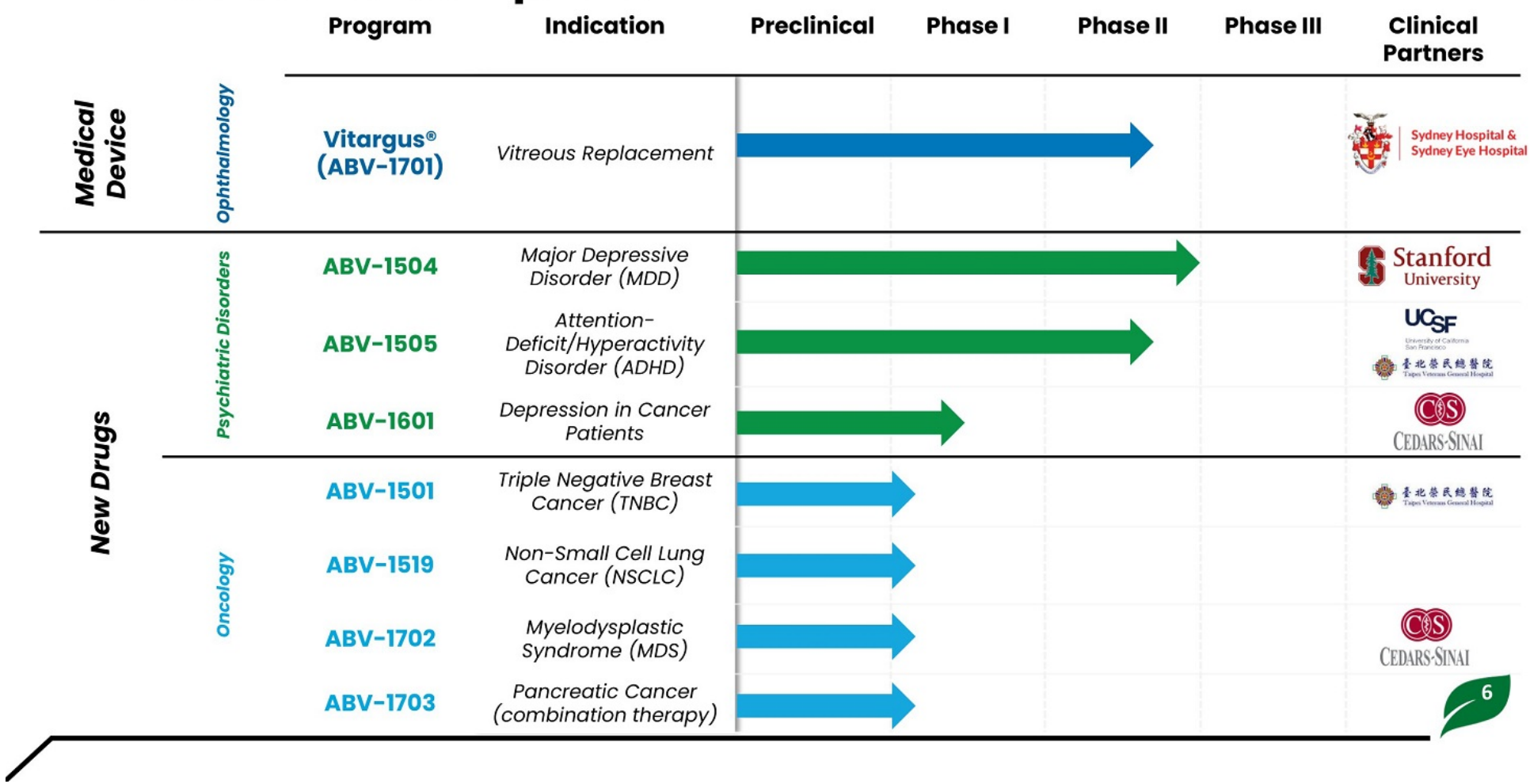
**Maurizio Fava, PhD**

**Susanna Cunningham-Rundles, PhD**

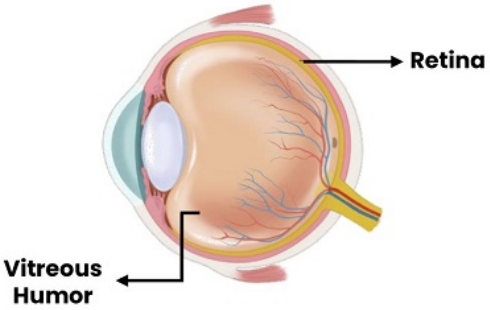
**Thomas Laughren, PhD**

**Keith McBurnett, PhD**

# Robust & Diverse Pipeline

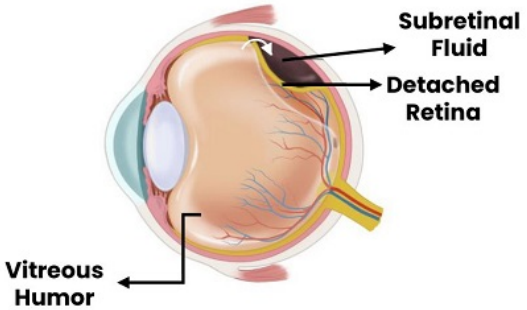


# Vitargus® for Retinal Detachment & Vitreous Hemorrhage



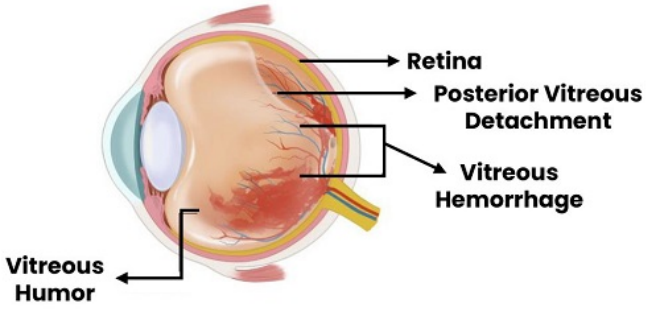

## Healthy Eye

***Vitargus®*** *is a Vitreous substitute that could potentially be used in retinal detachment and vitreous hemorrhage surgeries to accelerate healing and eliminate the need for a second surgery*




## Detached Retina

- Macular Hole
- Macular Pucker




## Vitreous Hemorrhage

- Diabetic Retinopathy
- Retinal Vein Occlusion
- Vitreous Body Injury

**Vitrectomy Surgery**

# Vitargus®: Solving an Unmet Need

## Key Takeaways

- Vitreous is a gel-like substance that helps the eye maintain a round shape and keeps the retina in place during and after retinal re-attachment surgery.
- **Current Vitreous substitutes** (Air, Silicone oil, Octafluoro-propane, Sulfur hexafluoride) **have disadvantages**[2, 3,4] that often lead to medical complications and additional surgeries
- **Leveraging Vitargus®, the patient does not need to remain in a face-down position and has improved visual acuity, as demonstrated in clinical trials**

**1 Functions of Vitreous Substitute**

- Fill up the vacant space after vitrectomy to maintain the eye shape
- Provide retina support for preventing re-detachment

**2 Current Short-term Vitreous Substitutes**

- Air, Octafluoropropane($C_3F_8$) or Sulfur hexafluoride($SF_6$)
- Readily absorbed
- **Maintaining face-down position (a week)**
- Retinal re-detachment easily

**3 Current Long-term Vitreous Substitutes**

- Silicone oil, Perfluoron™
- Emulsification
- **Requires a second surgery to remove**
- **Long-term implant complications**

**15% of retinal re-attachment surgeries fail with silicone oil[1]**




1. National Library of Medicine
2. Vitreous Substitutes: Old and New Materials in Vitreoretinal Surgery
3. Current Situation and Challenges in Vitreous Substitutes
4. Expert Reviews: Vitreous Substitutes

# Vitargus® Total Addressable Market

**~225,000** vitrectomies are performed annually in the U.S. alone[1]

**$2280** cost of Perfluoron Kit[3]
(sold by Alcon Labs and distributors)

**~$500M+ Annual Market**

**The U.S. remains the largest market, however, the demand in Asia-Pacific represents the fastest growing market[4]**

**ABVC plans to develop and commercialize Vitargus® in Asia and Europe prior to seeking FDA approval**

***Reimbursed indication growth[1, 2]***
*~900k patients with diabetic retinopathy in the U.S. have "vision-threatening" retinopathy but are not eligible for vitrectomy surgery due to age, coverage, and various other factors*



1. Vanderbilt University: Prospective Retinal and Optic Nerve Vitrectomy Evaluation Study
2. JAMA Ophthalmology
3. Grayline Medical; Medex Supply; Serfinity Medical
4. Mordor Intelligence: Vitreoretinal Survery Devices Market Size and Share Analysis

# Vitargus® for Retinal Detachment & Vitreous Hemorrhage

## *Vitargus® Advantages:*

*Best-in-Class Hydrogel Vitreous Substitute*

1. Aqueous formulation for ocular injection; Gelation within 3 minutes at body temperature & removes need to lie face down
2. Raw material is hyaluronic acid, a natural substance in the body
3. Biodegradable substance eliminates the need for second surgery
4. Does not cause emulsification like silicone oil occurred in some cases
5. Able to see clearly right after the treatment

| | Vitargus® | Air /Gas | Silicone Oil /Perfluoron |
|---|---|---|---|
| **Face up positioning** | ✓ | ✗ | ✗ |
| **1- day vision recovery** | ✓ | ✗ | ✗ |
| **Does not require 2nd surgery** | ✓ | ✓ | ✗ |

*Vitargus® is believed to be superior to current vitreous substitutes by reducing patient discomfort and need for second surgery while enabling a quick recovery*

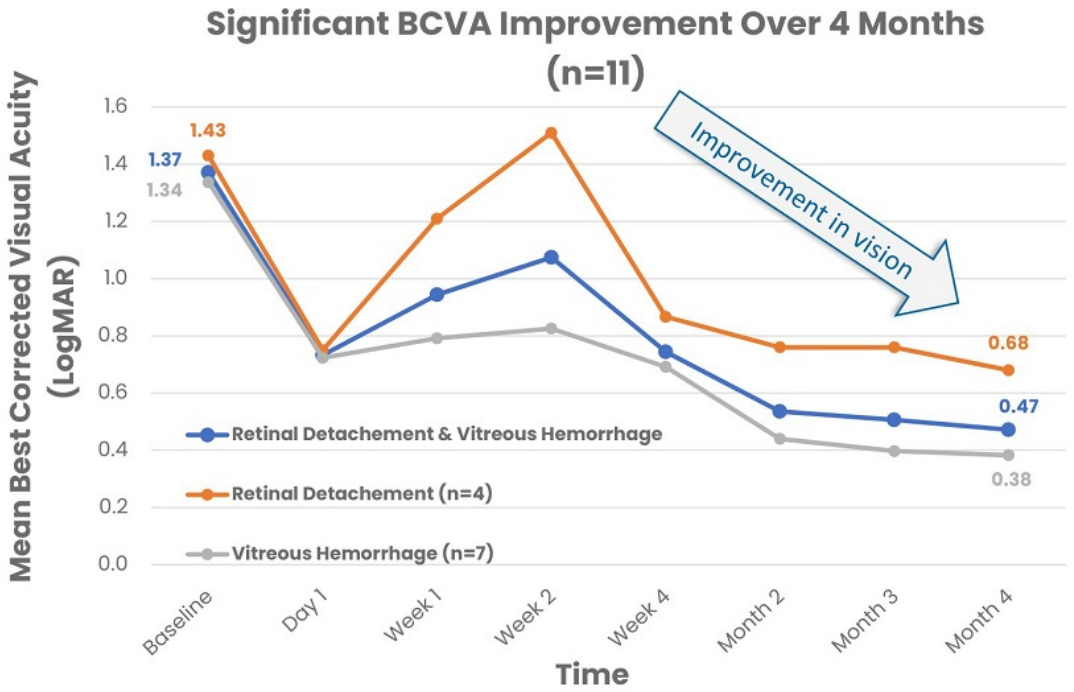


Results are based on internal clinical trials only; not verified by third parties

# Vitargus®: Completed First in Human Feasibility Study[1]

## Key Takeaways

- Vitargus® was **well-tolerated with no apparent toxicity** to ocular tissues
- A **statistically significant improvement** from baseline in best corrected visual acuity (BCVA)
- The optical properties of Vitargus® allowed the patients to see well and facilitated visualization of the fundus immediately following surgery.
- Vitargus® sets as a stable semisolid gel adhering to the retina and **maintains its position without the need of face-down positioning.**




***Best Corrected Visual Acuity (BVCA) is the standard to assess visual acuity, or 'sharpness of vision' measured by the ability to perceive letters and numbers. The lower score indicates the ability to read further down the ETDRS Chart.***



1. Retina 2019, Section IX: First-time Results of Clinical Trials, page 64
ETDRS: Early Treatment Diabetic Retinopathy Study

# Vitargus® Phase II Clinical Study

*Initiated in March 2023, expected to be completed 1H 2024*[1]

## Key Inclusion Criteria

- Uncomplicated retinal detachment, defined as the first instance of a small macular hole and retinal tears.
- Diagnosis of vitreous hemorrhage that requires vitrectomy surgery.
- BCVA (Best Corrected Visual Acuity) of 20/40 to 20/2000.
- Able to provide written informed consent, attend all scheduled visits, and comply with all study procedures.

## Multi-center, randomized open-label n=40

**Active Vitargus® Arm (n=20)**

Enrolling 20 patients to receive Vitargus® in conjunction with a Vitrectomy

**Active Comparator Arm (n=20)**

Enrolling 20 patients to receive $SF_6$ Gas OE in conjunction with a Vitrectomy

**Primary Endpoint**

To assess the safety and effectiveness of the ABV-1701 OE when compared to the $SF_6$ Gas OE.

**Key Secondary Endpoints**

1. Efficacy for retinal attachment repair
2. Hydrogel degradation at day 90
3. Best Corrected Visual Acuity (BCVA) post Vitrectomy

*The unique properties of Vitargus® hold promise for its use following a vitrectomy.* [2]

***-Andrew Chang, MBSS, PhD***

*American Academy of Ophthalmology (AAO) 2019, San Francisco*



1. Clinicaltrials.gov (NCT05414747)
2. Retina 2019, Section IX: First-time Results of Clinical Trials, page 64

*A safe in-situ procedure for Vitargus® hydrogel formation is currently being developed to avoid Serious Adverse Events (SAEs) observed during the early Phase II study in Thailand sites*

# Botanical-Based Pipeline for Psychiatric Disorders

***Developing a suite of botanical-based assets to combat rising addiction***

| | **ABV-1504**<br>*Major Depression Disorder (MDD)* | **ABV-1505**<br>*Attention-Deficit/Hyperactivity Disorder (ADHD)* | **ABV-1601**<br>*Depression in Cancer Patients* |
|---|---|---|---|
| **Clinical Status** | **Phase II completed** | **Phase IIa completed, Phase IIb in progress** | **Phase I initiated** |
| **Safety** | **No SAE's directly from the drug have been reported** | **No SAE's directly from the drug have been reported** | **No SAE's directly from the drug have been reported** |
| **U.S. Addressable Patient Population** | **~9 million adults** (medication-treated MDD[1]) | **~11 million adults**[5] | ~1.9 million newly diagnosed cancer patients / year[6] **(~247k w/ depression[7])** |
| **U.S. Market Size** | **~$12.4 billion**[2] | **~$10 billion**[3,4] | **~$342 million annually**[2] |



1. National Library of Medicine: Major Depressive Disorder (MDD) Prevalence
2. National Library of Medicine: MDD Drug Cost Comparison
3. ADHD Statistics and Facts
4. SingleCare: 2022 ADHD Medication Costs
5. Attention Deficit Disorder Association: ADHD Facts
6. American Cancer Society: Cancer Facts & Figures 2022
7. National Library of Medicine: Prevalence of Depression in Cancer Patients

# ABV-1504: Innovative Botanical Asset for MDD

## IP-Protected Process

1. *Raw Materials (dry roots of Yuan Zhi)*
2. *Extraction*
3. *Purification*
4. *Isolation*
5. *Encapsulation*

**No methylation process required**

## ABV-1504 Summary Highlights

- ABV-1504 (PDC-1421 capsule) is a single-herb botanical drug extract from the dry root of *Polygala tenuifolia* Willd
- **Safety assessment:** Demonstrated its safety with no SAEs from the completed Phase I and Phase II studies.
- **Efficacy assessment:** Demonstrated its efficacy for treating Major Depressive Disorder (MDD) patients from the Phase II clinical studies.
- **Stability at least 36 months** post encapsulation



Outcomes cannot be guaranteed; Past results are not guarantees of future results
Summary Highlights are based on internally generated data

SAEs: Serious Adverse Events

# ABV-1504 Completed Phase I Highlights

## Key Takeaways

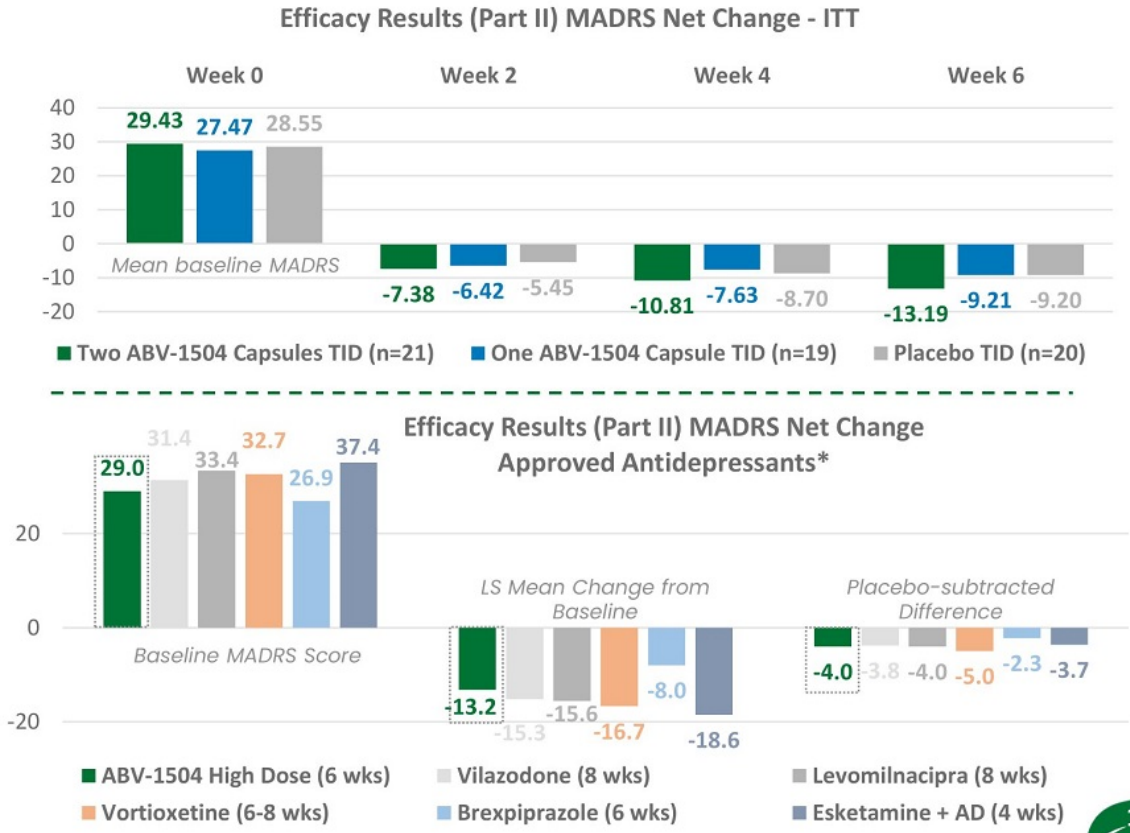
- The oral administration of ABV-1504 Capsules in healthy volunteers was safe and well-tolerated for doses from 380 mg to 3,800 mg
- No subject had serious adverse event and no subject discontinued due to adverse event

| Phase of Development | Phase I |
|---|---|
| **Investigational product** | **ABV-1504 (PDC-1421 capsule, extract of *Radix Polygalae*)** |
| **Unit dose** | **380 mg** |
| **Mode of administration** | **Oral** |
| **Study title** | **A Dose Escalation Phase I Study of PDC-1421 Capsule to Evaluate the Safety in Health Volunteers** |
| **Administrated units** | **1,3, 6, 10 capsules, Once daily after meal** |
| **Number of subjects** | **30 evaluated** |
| **Center** | **Taipei Veterans General Hospital (TVGA)** |

# ABV-1504 Completed Phase II Highlights

## Key Takeaways

- The High-Dose group (760 mg TID) of ABV-1504 **demonstrated a clinically meaningful score in MADRS compared to the Placebo group.**
- Compared with prior approved Fluoxetine(Prozac) antidepressant, **ABV-1504 High-Dose demonstrated a much better MADRS score (4.1-point reduction ) from Placebo group** than that of Fluoxetine (2.3-point reduction).
- Treatment of ABV-1504 did not increase any risks in terms of vital signs, physical exams, suicidal ideation, and suicidal behavior during treatment and follow-up period.
- No severe adverse events (SAEs) occurred.
- Demonstrated ABV-1504 was safe and well-tolerated for further clinical advancement.






MADRS: Montgomery–Åsberg Depression Rating Scale
TID: Three times daily

*Values taken as the median of ranges collected, see appendix for detailed data ranges*
Outcomes cannot be guaranteed; Past results are not guarantees of future results

# ABV-1504 Phase III Clinical Plan

*Plans to initiate after the end of Phase II meeting with the FDA expected in 2023*

## Key Inclusion Criteria

- Outpatient adults 18-75 years old
- Met criteria for MDD without psychotic features as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Test Revision (DSM-IV-TR)
- 17-item HAM-D total score ≥ 20 and CGI total score ≥ 4

## Multi-National, Randomized (1:1:1), Double Blind Study n=60

- Participants to receive one 380mg ABV-1504 capsule and one placebo three times / day (TID)
- Participants to receive two 380mg ABV-1504 capsule three times / day (TID)
- Participants to receive two placebo capsules three times / day (TID)

## Primary Endpoint

Change from Baseline to Week 8 on the MADRS (Montgomery-Asberg Depression Rating Scale) total score

## Key Secondary Endpoints

1. HAM-D-17, CGI, SDS, and HAM-A change from baseline to Week 2, 6 and 8)
2. Percentage of responders (defined as ≥ 50% decrease from baseline in total score) in MADRS by Week 6 and 8
3. Percentage of participants in MADRS remission at Week 6 and 8 (remission defined as MADRS total Score ≤ 10)

*Plant-derived treatments may be more attractive to patients with depression, who may be hesitant to take pharmaceuticals.*

***-Charles DeBattista, MD***

*Professor of Psychiatry and Behavioral Sciences, Stanford University*



MADRS: Montgomery-Asberg Depression Rating Scale
HAM-D-17: Hamilton Rating Scale for Depression
CGI: Clinical Global Impression
SDS: Sheehan Disability Scale
HAM-A: Hamilton Rating Scale for Anxiety
Outcomes cannot be guaranteed; Past results are not guarantees of future results

# ABV-1505: Innovative Botanical Asset for ADHD

## IP-Protected Process

1. *Raw Materials (dry roots of Yuan Zhi)*
2. *Extraction*
3. *Purification*
4. *Isolation*
5. *Encapsulation*

**No methylation process required**

## ABV-1505 Summary Highlights

- ABV-1505 (PDC-1421 capsule) is a single-herb botanical drug extract from the dry root of Polygala tenuifolia Willd
- **Safety assessment:** Demonstrated its safety with no SAEs from the completed Phase I and Phase II (Part I) clinical studies.
- **Efficacy assessment:** Demonstrated its efficacy for treating ADHD patients from the completed Phase II clinical studies (Part I).
- IP Protection: Global patent granted including US, EU and Asian countries.



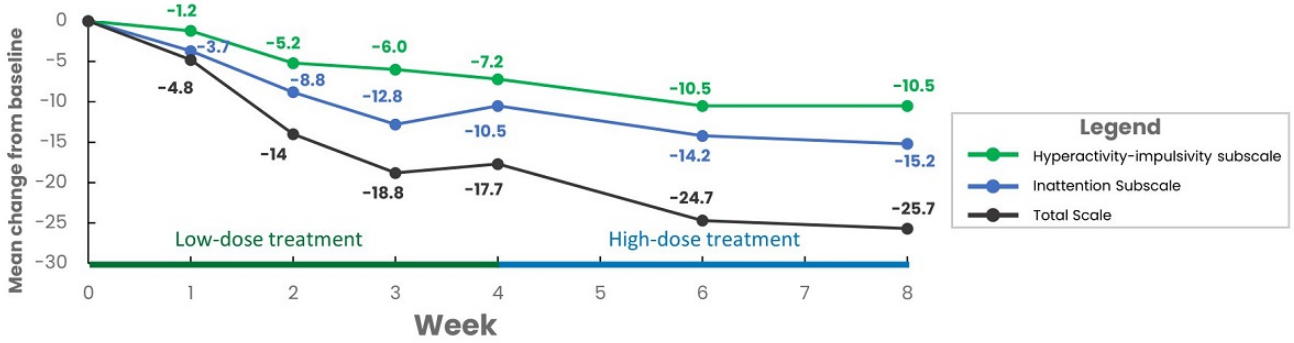
Outcomes cannot be guaranteed; Past results are not guarantees of future results
Summary Highlights are based on internally generated data

# ABV-1505 Completed Phase IIa in Adults with ADHD[1]

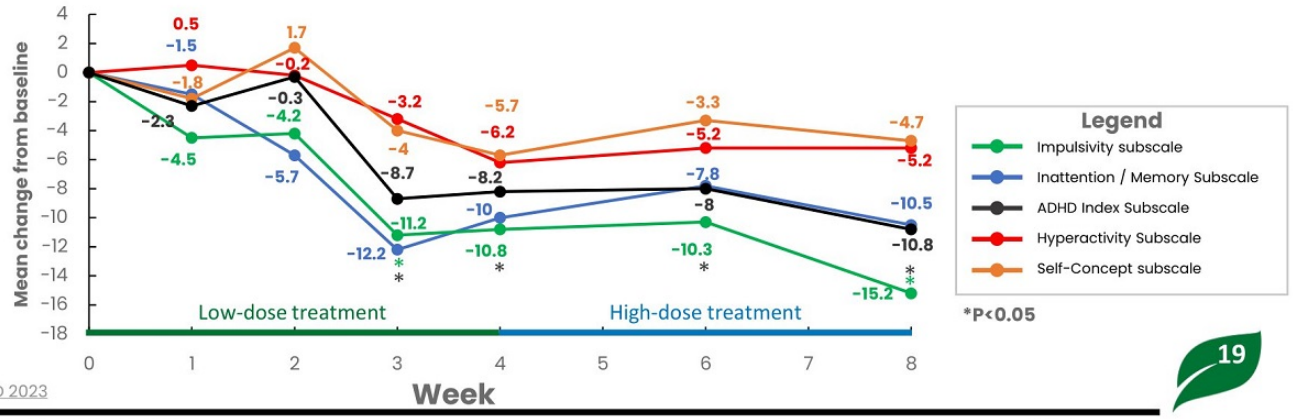
## Key Takeaways

- Mean change of ADHD-RS-IV Score from baseline to 8 weeks treatment were:
  - **83.3% (5/6) subjects** in the ITT population **and 80% (4/5) subjects** in the PP population **achieved an improvement of 40% or greater in ADHD Rating Scale** (Primary Endpoint).
- Mean change in CAARS-S:S from baseline to 8 weeks treatment were:
  - **-10.8 and -15.2 (p=.0313) in the ITT population**
  - **-10.6 and -14.0 (p=.0625) in the PP population**
- No severe adverse events (SAEs)or deaths occurred.

### ITT Population Mean Change of ADHD-RS-IV Score from Baseline




### ITT Population Mean Change of CAARS:S-S Score from Baseline




*P<0.05

1. ABVC BioPharma Presents ABV-1505 Phase IIa Results at APSARD 2023

PP: Per-Protocol Population
ITT: Intention-to-Treat Population

ADHD-RS-IV: ADHD Rating Scale-Investigator Rated
CAARS:S-S: Conners' Adult Attention-Deficit/Hyperactivity Disorder (ADHD) Rating Scale – Self Report: Short Version

Outcomes cannot be guaranteed; Past results are not guarantees of future results

# ABV-1505 Phase IIb Clinical Plan

*Initiated April 2022, expected to be completed by end of 2023*

The study will enroll 69 subjects initially. After 8 weeks, an interim analysis will be conducted to determine if it is necessary to enroll an additional 30 subjects

## Key Inclusion Criteria

- Ability to discontinue use of psychotropic medications for the treatment of ADHD symptoms at screening
- Meet operational criteria for Adult ADHD according to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5)
- Total score of 28 or higher of ADHD Rating Scale-Investigator Rated (ADHD-RS-IV)
- Have moderate or severe symptoms of ADHD with a score of 4 or higher in Clinical Global Impression-Severity (CGI-S) at screening

## Multi-center, Randomized (1:1:1), Double-Blind, Placebo-controlled (n=99)

Participants to receive one 380mg ABV-1504 capsule and one placebo three times / day (TID)

Participants to receive one 380mg ABV-1504 capsule and one placebo three times / day (TID)

Participants to receive one 380mg ABV-1504 capsule and one placebo three times / day (TID)

## Primary Endpoint

Improvement of 40% or more in ADHD Rating Scale-Investigator Rated (ADHD-RS-IV) from baseline to 8 weeks

## Key Secondary Endpoints

1. Safety and incidence of Adverse Events and Serious Adverse Events
2. Symptom Remission in ADHD-RS-IV total score ≤ 18 up to 8 weeks
3. Change from baseline in ADHD-RS-IV, CAARS-S:S and E-SCT score up to 8 weeks
4. CGI-I score of 2 or lower up to 8 weeks treatment

*Based on its well-tolerated safety profile and preliminary efficacy shown in Phase IIa study, ABV-1505 has promise as a treatment for ADHD.**

***-Keith McBurnett, PhD***

*Professor of Psychiatry at UCSF, San Francisco*

*As stated at the 2023 Conference of the American Professional Society of ADHD and Related Disorders (APSARD) Poster Session

ADHD-RS-IV: ADHD Rating Scale-Investigator Rated
CAARS-S:S: Conners' Adult ADHD Rating Scale – Self Report
CGI: Clinical Global Impression
E-SCT: Empirical-Sluggish Cognitive Tempo
CGI-I: Clinical Global Impression - Improvement
Outcomes cannot be guaranteed; Past results are not guarantees of future results

# ABV-1601 Phase I Clinical Plan

*Initiated April 2022, expected to be completed by end of 2023*

## Key Inclusion Criteria

- Confirmed diagnosis of Stage I, II, or III cancer & Histologically-proven malignancy
- Receiving or within one year of receiving cancer treatment with radiation and/or chemotherapy
- Montgomery-Åsberg Depression Rating Scale (MADRS) ≥ 20 (moderate to severe depressive symptoms)
- Duration of depressive symptoms ≥ 2 weeks by patient report.
- No active/acute suicidality requiring immediate care or psychiatric hospitalization

## Single-Center, Open-Label Study (n=12)

6 participants to receive one ABV-1601 capsule three times / day (TID) for 28 days

6 participants to receive two ABV-1601 capsules three times / day (TID) for 28 days

*Dose escalation*

**One ABV-1601 (PDC-1421) Capsule TID**

**Two ABV-1601 (PDC-1421) Capsules TID**

*Week 1* *Week 2* *Week 3* *Week 4*

## Primary Endpoint

Safety, AE's, and SAE's related to ABV-1601

Score on the Therapeutic Effect subscale of the CGI Efficacy Index

Score on the Side Effects subscale of the CGI Efficacy Index

Score on FIBSER questionnaire
C-SSRS rating scale

## Key Secondary Endpoints

1. Change in MADRS total score and HADS total score from baseline to Week 1-5

*Scott Irwin, MD, Ph.D., and the lead investigator of this study are continuing to work towards understanding the safety of ABV-1601 at similar doses in several other studies.*

***-Scott Irwin, MD, PhD***
*Professor of Psychiatry & Behavioral Neurosciences, Cedar-Sinai*



AE's: Adverse Events
SAEs: Serious Adverse Events

CGI: Clinical Global Impression
CSSRS: Columbia-Suicide Severity Rating Scale

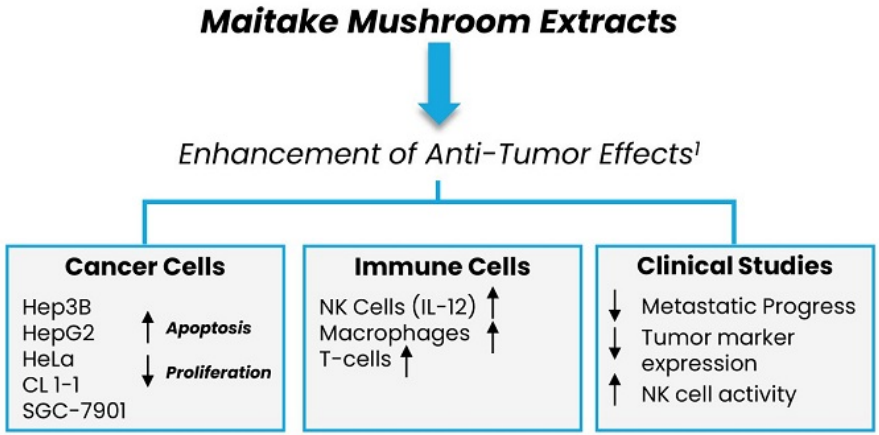
MADRS: Montgomery-Asberg Depression Rating Scale
HADS: Hospital Anxiety and Depression Scale

Outcomes cannot be guaranteed; Past results are not guarantees of future results

# Early-Stage Oncology Pipeline Overview

## Maitake API Overview: BLEX 404

- The API of our early-stage oncology portfolio is **BLEX 404, a beta-glucan characterized by a beta-1,6-linked glucose core** with beta-1,3-linked glucose branches and beta-1,3-linked glucose core with beta-1,6-linked glucose branches
- The drug substance, **BLEX 404 used for the study is the MD-fraction of *Grifola frondosa*, extracted and fractionated from mycelia and fruit bodies of Maitake mushroom.**
- The drug product BLEX 404 is formulated into an oral liquid dosage form (40 mg/mL of BLEX 404).






1. Effect of Maitake (*Grifola frondosa*) D-Fraction on the activation of NK cells in cancer patients

API: Active Pharmaceutical Ingredient

# Early-Stage Oncology Pipeline Overview (Cont.)

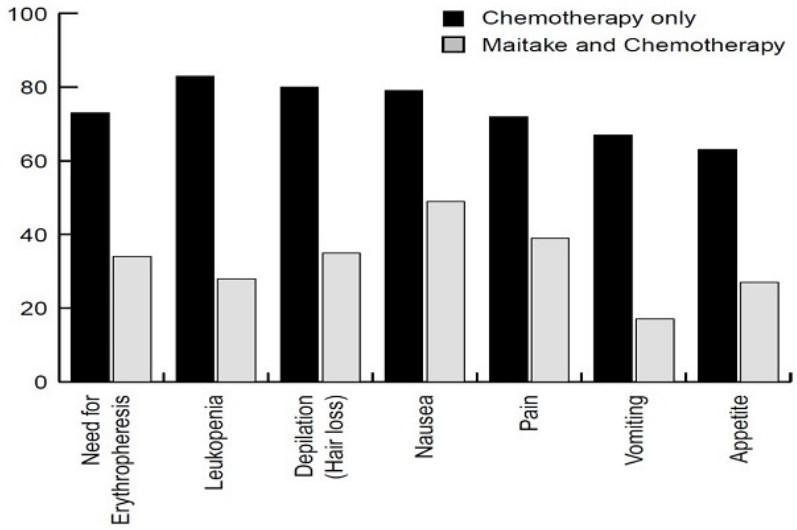
## External Research Demonstrating Improved Cancer Symptoms with Maitake Mushroom[1]

Nonrandomized clinical trial with Maitake D-Fraction

22–57-year-old cancer patients (Stage II-IV cancers)

| Cancer regression or significant symptom improvement | < 10-20% Improvement |
|---|---|
| 58.3% Liver cancer patients (11/16) | Leukemia patients |
| 68.8% Breast cancer patients (7/12) | Stomach cancer patients |
| 62.5% Lung cancer patients (5/8) | Brain cancer patients |

## Amelioration of chemotherapeutic side-effects[1]






1. National Library of Medicine: Can Maitake MD-Fraction Aid Cancer Patients

# Near-Term Milestones & Use of Proceeds

| Asset | Indication | 1H 2023 | 2H 2023 | 1H 2024 | 2H 2024 |
|---|---|---|---|---|---|
| **Vitargus® (ABV-1701)** | *Vitreous Replacement* | **Completion of Phase II Study** | | | **Planning Phase III** |
| **ABV-1504** | *Major Depressive Disorder (MDD)* | ★ *IP Granted* | **Completion End-of-Phase II Meeting** | | **Planning Phase III** |
| **ABV-1505** | *Attention-Deficit/Hyperactivity Disorder (ADHD)* | **Completion Phase IIb Study** | | ★ *IP Granted* | **Completion End-of-Phase II Meeting** |
| **ABV-1601** | *Depression in Cancer Patients* | **Completion Phase I Study** | | **Completion Phase II Study** | |
| **Projected Cash Burn** | | ***~$2.2M*** | ***~$2.4M*** | ***~$2.7M*** | ***~$3M*** |

***Multiple near-term clinical catalysts expected by the end of 2023***

ABVC BIOPHARMA

**NASDAQ: ABVC**

Howard Doong
44370 Old Warm Springs Blvd.
Fremont, California 94538

Office: (510) 668-0881
howard.doong@ambrivis.com

Investor Relations Contact:

Tom Masterson
(646) 573-3216
tmasterson@allelecomms.com

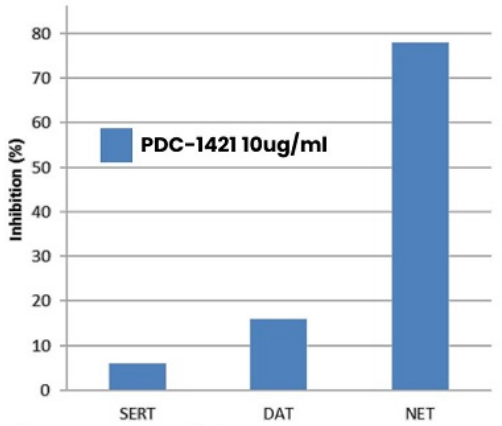
# Mechanism of Action: PDC-1421

*PDC-1421 is the active pharmaceutical ingredient in ABV-1504, -1505, and -1601*

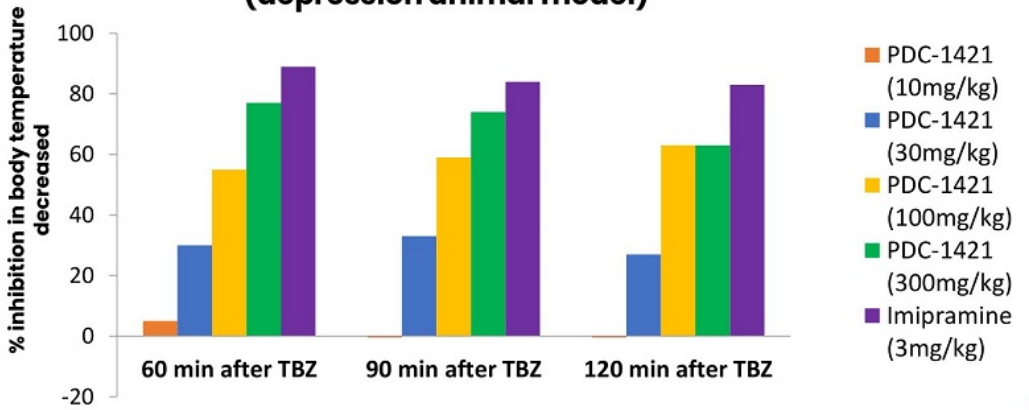
***PDC-1421 is a norepinephrine reuptake inhibitor, demonstrating a significant response at 100mg/kg and 300mg/kg doses in a preclinical depression animal model***

***The unique properties and known Mechanism of Action (MOA) of PDC-1421 enable us to expand to different indications, such as MDD, ADHD, and depression in cancer patients***

| Assay Name | $IC_{50}$ (μg/mL) |
|---|---|
| Norepinephrine Transporter | **1.6** |
| Dopamine Transporter | **76.4** |
| Serotonin Transporter | **> 300** |




**Tetrabenazine (TBZ)-induced Hypothermia Model (depression animal model)***






* The inhibition by ≧ 50% is considered as significant response. Imipramine served as a positive control.

DAT: Dopamine transporter
SERT: Serotonin transporter
NET: Norepinephrine transporter

# ABV-1504 Phase IIb Data

## Key Takeaways

- The High-dose group (760 mg TID) ofABV-1504 **demonstrated a clinically meaningful score in MADRS compared to Placebo group.**
- Compared with prior approved Fluoxetine(Prozac) antidepressant, **ABV-1504 High-Dose demonstrated a much better MADRS score (4.1-point reduction ) from Placebo group** than that of Fluoxetine (2.3-point reduction).
- Treatment of ABV-1504 did not increase any risks in terms of vital signs, physical exams, suicidal ideation, and suicidal behavior during treatment and follow-up period.
- No severe adverse events (SAEs) occurred.
- Demonstrated ABV-1504 was safe and well-tolerated for further clinical advancement.

| Indication | Compound | Treatment Period | Baseline MADRS Score | LS Mean Change from Baseline | Placebo-subtracted Difference |
|---|---|---|---|---|---|
| **MDD** | **ABV-1504 High Dose (PDC-1421)** | **6 wks** | **28.6 to 29.4** | **-13.2** | **-4.0** |
| MDD | Vilazodone (VIIBRYD®) | 8 wks | 30.7 to 32.0 | -12.9 to -17.6 | -2.5 to -5.1 |
| MDD | Levomilnacipra (FETZIMA®) | 8 wks | 30.7 to 36.1 | -14.4 to -16.8 | -3.1 to -4.9 |
| MDD | Vortioxetine (TRINTELLIX®) | 6-8 wks | 31.2 to 34.1 | -13.0 to -20.4 | -2.8 to -7.1 |
| Adjunctive MDD | Brexpiprazole (REXULTI®) | 6 wks | 26.5 to 27.3 | -7.6 to -8.4 | -1.3 to -3.2 |
| TRD | Esketamine + AD (SPRAVATO®) | 4 wks | 37.0 to 37.8 | -18.2 to -18.9 | -3.2 to -4.1 |