

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





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

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

- ✓ 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





Sydney Hospital & Sydney Eye Hospital



Memorial Sloan Kettering Cancer Center

Leadership Team









Robust & Diverse Pipeline

		Program	Indication	Preclinical	Phase I	Phase II	Phase III	Clinical Partners
Medical Device	Ophthalmology	Vitargus® (ABV-1701)	Vitreous Replacement					Sydney Hospital & Sydney Eye Hospita
sɓr	rders	ABV-1504	Major Depressive Disorder (MDD)					Stanford University
	Psychiatric Diso	ABV-1505	Attention- Deficit/Hyperactivity Disorder (ADHD)					University of California San Francisco 愛記祭氏總督院 Taipei Veteraus General Hospital
		ABV-1601	Depression in Cancer Patients					CEDARS-SINAI
W Dr	Oncology	ABV-1501	Triple Negative Breast Cancer (TNBC)					臺北奈民總醫兌 Tapei Veterans General Hospital
Ne		ABV-1519	Non-Small Cell Lung Cancer (NSCLC)					
		ABV-1702	Myelodysplastic Syndrome (MDS)					CEDARS-SINAI
		ABV-1703	Pancreatic Cancer (combination therapy)					6

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, Octafluoropropane, 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



- Fill up the vacant space after vitrectomy to maintain the eye shape
- Provide retina support for preventing re-detachment
- Air, Octafluoropropane(C_3F_8) or Sulfur hexafluoride(SF₆)
- Readily absorbed
- Maintaining face-down position (a week)
- Retinal re-detachment easily
- Silicone oil, Perfluoron[™]
- Emulsification
- **Requires a second surgery to remove**
- Long-term implant complications

15% of retinal re-attachment surgeries fail with silicone oil¹

National Library of Medicine

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. alone¹

\$2280 cost of Perfluoron Kit³ (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 market⁴

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

Vitargus® for Retinal Detachment & Vitreous Hemorrhage

Vitargus[®] Advantages:

Best-in-Class Hydrogel Vitreous Substitute

- Aqueous formulation for ocular injection; Gelation within 3 minutes at body temperature & removes need to lie face down
- Raw material is hyaluronic acid, a natural substance in the body
- Biodegradable substance eliminates the need for second surgery



5

Does not cause high intraocular pressure (low thermal expansion coefficient)





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



Vitargus®: Completed First in Human Feasibility Study¹



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.

Vitargus® Phase II Clinical Study

Initiated in March 2023, expected to be completed 1H 2024¹



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 SF₆ Gas OE in conjunction with a Vitrectomy

Primary Endpoint

To assess the safety and effectiveness of the ABV-1701 OE when compared to the SF₆ 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

12

1. <u>Clinicaltrials.gov (NCT05414747)</u>

2. <u>Retina 2019, Section IX: First-time Results of Clinical Trials, page 64</u>

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 Major Depression Disorder (MDD)	ABV–1505 Attention-Deficit/Hyperactivity Disorder (ADHD)	ABV–1601 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. <u>SingleCare: 2022 ADHD Medication Costs</u>5. Attention Deficit Disorder Association: ADHD Facts

6. <u>American Cancer Society: Cancer Facts & Figures 2022</u> 7. National Library of Medicine: Prevalence of Depression in Cancer Patients

ABV-1504: Innovative Botanical Asset for MDD



IP-Protected Process



ABV-1504 Summary Highlights

- ABV-1504 (PDC-1421 capsule) is a singleherb 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

ABV-1504 Completed Phase I Highlights



Key Takeaways

- The oral administration of ABV-1504 Capsules in healthy volunteers was safe and welltolerated 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 <i>Radix</i> 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 Healthy 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 (4.1point 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.



Efficacy Results (Part II) MADRS Net Change - ITT

*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)
- Percentage of responders (defined as ≥ 50% decrease from baseline in total score) in MADRS by Week 6 and 8
- 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









No methylation process required

ABV-1505 Summary Highlights

- ABV-1505 (PDC-1421 capsule) is a singleherb 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.



ABV-1505 Completed Phase IIa in Adults with ADHD¹





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

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 CAARS:S-S Score from Baseline



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

lation 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
- 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



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

One ABV-1601 (PDC-1421) Capsule TID

Two ABV-1601 (PDC-1421) Capsules TID

Week 1 Week 2

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
Key Secondary Endpoints



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

Week 3

Professor of Psychiatry & Behavioral Neurosciences, Cedar-Sinai

Week 4



AE's: Adverse Events SAEs: Serious Adverse Events CGI: Clinical Global Impression CSSRS: Columbia-Suicide Severity Rating Scale

Dose escalation

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-1,3linked 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).





External Research Demonstrating Improved Cancer Symptoms with Maitake Mushroom¹



Amelioration of chemotherapeutic sideeffects¹

BIOPHARMA



Near-Term Milestones & Use of Proceeds





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

ABVC

BIOPHARMA

NASDAQ: ABVC

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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





^{*} The inhibition by ≥ 50% is considered as significant response. Imipramine served as a positive control.

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

decreased

60

40

20

0

-20

60 min after TBZ

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

90 min after TBZ



ABV-1504 Phase IIb Data

Key Takeaways

- The High-dose group (760 mg TID) of ABV-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