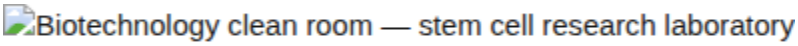
BREATHE BIOLOGICS, INC.

Transforming Hope Into Healing

Press-Ready Media Kit

JadiCell™ | ARDS | Investigational UC-MSC Therapy

September 2026 | Clinical-Stage Biopharmaceutical



JadiCell™ is a patented technology derived from the subepithelial layer of umbilical cord tissue and manufactured as an allogeneic mesenchymal cell therapy under cGMP standards.

Media Inquiries

This media kit is intended for journalists, science editors, healthcare reporters, financial media, and investor relations professionals.

Embargoed materials available upon request.

Contact information provided in Section 9 of this document.

⚠ **Required Regulatory Notice**

JadiCell™ is an investigational therapy and has not been approved by the FDA for any indication. All clinical data referenced in this document are from early-phase investigational studies. This material is intended solely for media background purposes and does not constitute medical advice, investment guidance, or promotional claims regarding an unapproved product.

Section 1 Company at a Glance

Breathe Biologics, Inc. is a clinical-stage biopharmaceutical company pioneering an investigational cell therapy — **JadiCell™** — designed to address one of medicine's most urgent and underserved crises: Acute Respiratory Distress Syndrome (ARDS). With peer-reviewed Phase 1/2a clinical data published in *STEM CELLS Translational Medicine* and a pivotal Phase 2b/3 trial in preparation, Breathe Biologics is advancing what may become the first disease-modifying pharmacologic therapy for ARDS.

91% Survival Rate at Day 31 (JadiCell™ group)	**2 vs. 16** Serious Adverse Events (JadiCell™ vs. Control)	**128** Patients Planned Phase 2b/3 Pivotal Trial

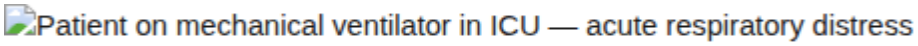
Company Type	
Headquarters	United States
Lead Program	JadiCell™ — Patented Investigational Technology Derived from the Subepithelial Layer of Umbilical Cord Tissue
Key Milestone	Phase 1/2a clinical trial published in *STEM CELLS Translational Medicine* (2021)
Pipeline Stage	Phase 2b/3 Pivotal Trial in Preparation — NCT07479043 | IND #19757
U.S. Patent	U.S. Patent No. 9,803,176 B2

Company Type	
Manufacturing	cGMP Standards
Tagline	*"Transforming Hope Into Healing"*

Key Differentiator

JadiCell™ is a patented technology derived from the subepithelial layer of umbilical cord tissue. It is manufactured in advance as an allogeneic, off-the-shelf cell therapy and requires no cell harvesting from individual patients. This makes it uniquely scalable for emergency critical care settings where time is a matter of life and death.

Section 2 The Problem — ARDS: A Silent Crisis



For ARDS patients, survival often depends on mechanical ventilation — a life-sustaining intervention with no pharmacologic cure currently available.

Every year, more than **190,000 Americans** are struck by Acute Respiratory Distress Syndrome — a catastrophic inflammatory failure of the lungs that can progress from onset to mechanical ventilation in hours. Despite the staggering human toll, ARDS kills quietly: it has no ribbon, no widely recognized awareness campaign, and — until now — no FDA-approved pharmacologic therapy targeting its root cause.

ARDS claims between **30 and 45 percent** of those it afflicts, making it deadlier each year than breast cancer in terms of annual U.S. fatalities. Patients who survive often face permanent lung damage, prolonged ICU stays, and months of rehabilitation. For families, the onset of ARDS can mean walking into a hospital expecting treatment for pneumonia or flu and walking out without their loved one.

The pathology is merciless. When ARDS strikes — triggered by infection, trauma, sepsis, or severe respiratory illness — the immune system misfires catastrophically. Inflammatory signals called cytokines flood the lungs in a phenomenon widely known as a "cytokine storm," causing fluid accumulation, tissue

destruction, and a progressive loss of the ability to breathe. Physicians treat the symptoms: supplemental oxygen, mechanical ventilation, prone positioning. But no medicine has ever been shown, in a randomized controlled trial, to modify the underlying inflammatory cascade and improve survival outcomes.

The economic burden is equally staggering. ARDS costs the U.S. healthcare system **more than $1 billion annually**, driven by prolonged mechanical ventilation, ICU resource utilization, and long-term post-ARDS rehabilitation costs. Healthcare systems from community hospitals to major academic medical centers carry this burden — quietly, year after year.

> ⚠ **The Treatment Gap**
>
> Despite decades of research and numerous failed clinical trials, **there is currently no FDA-approved pharmacologic therapy that targets the root cause of ARDS**. Breathe Biologics is developing what could be the first such treatment.

ARDS at a Glance — The Scope of the Crisis

Metric	Data Point
Annual U.S. Cases	190,000+
Mortality Rate	30–45%
Annual U.S. Economic Burden	Exceeds $1 billion
FDA-Approved Pharmacologic Therapies	None targeting root cause
Primary Intervention	Mechanical ventilation (supportive only)
Primary Trigger Categories	Pneumonia, sepsis, trauma, viral respiratory illness

Section 3 The Breakthrough — JadiCell™ Technology

What Is JadiCell™?

JadiCell™ is Breathe Biologics' patented investigational technology, derived from the subepithelial layer of umbilical cord tissue and manufactured as an allogeneic mesenchymal cell therapy under current Good Manufacturing Practice (cGMP) standards. "Allogeneic" means the cells come from a universal donor source — in this case, donated umbilical cord tissue — rather than from the patient being treated. This is the defining practical advantage of JadiCell™: it can be manufactured at scale, stored, and deployed rapidly, even in emergency critical care settings.

How It Works — In Plain Language

ARDS is, at its core, an immune system in overdrive. The body's defensive inflammatory response — intended to fight infection or heal injury — spirals out of control, releasing a cascade of inflammatory proteins (cytokines) that destroy lung tissue faster than the body can repair it. JadiCell™ is designed to interrupt this cycle.

When infused intravenously, JadiCell™ cells are understood to act on the immune system's signaling pathways, helping to **calm the cytokine storm** and shift the immune response from an attack mode to a repair mode. Rather than simply suppressing immune function globally — which can leave patients vulnerable to further infection — JadiCell™ is hypothesized to help the body recalibrate toward healing. The result, as observed in early clinical data, is a meaningful reduction in inflammatory markers and a significant improvement in survival outcomes.

Why JadiCell™ Is Different

- **Off-the-shelf availability:** No patient cell harvesting or personalized manufacturing required — critical for a disease where hours matter.
- **Defined tissue origin: JadiCell™ is derived from the subepithelial layer of donated umbilical cord tissue, a neonatal source with characteristics that support allogeneic use.**
- **Patented technology: JadiCell™ is derived from the subepithelial layer of umbilical cord tissue and is protected by U.S. Patent No. 9,803,176 B2; it is not a generic MSC product.**
- **Scalable manufacturing:** Produced under cGMP standards ensuring quality, consistency, and the ability to scale production for a Phase 2b/3 pivotal trial and beyond.

- **Novel mechanism in ARDS:** JadiCell™ targets the inflammatory cascade at the cytokine level — the first investigational approach of its kind in ARDS to generate this class of Phase 1/2a clinical evidence.

> *"UC-MSC infusions were safe and showed no treatment-related adverse events."*
>
> — STEM CELLS Translational Medicine (2021), reporting on the Phase 1/2a randomized controlled trial of JadiCell™ in ARDS patients

IP & Manufacturing Summary

Patent: U.S. Patent No. 9,803,176 B2

Cell Source: Subepithelial layer of donated umbilical cord tissue

Administration: Intravenous infusion

Trial Regulatory Ref.: IND #19757

Section 4 Clinical Evidence — The Data Story

The Phase 1/2a Trial: A Story Worth Telling

In the halls of one of America's foremost academic medical centers, a small but rigorously conducted clinical trial began to answer one of modern medicine's most stubborn questions: can a cell therapy interrupt the runaway inflammation that kills ARDS patients?

Investigators enrolled **24 ARDS patients** in a double-blind, randomized, placebo-controlled Phase 1/2a clinical trial evaluating JadiCell™. The trial was designed with scientific rigor — the gold standard of randomized control — and its results were subsequently published in the peer-reviewed journal *STEM CELLS Translational Medicine* in 2021, one of the field's leading scientific publications.

The findings were striking — and statistically significant.

Key Results — For Media Use

91% Day-31 Survival JadiCell™ Group	**42%** Day-31 Survival Placebo Group	**P = 0.015** Statistical Significance (Survival)

Outcome Measure	JadiCell™ Group	Control / Placebo Group	Statistical Result
Survival at Day 31	91%	42%	P = 0.015 (significant)
Serious Adverse Events (SAEs)	2	16	P = 0.008 (significant)
Time to Recovery	Significantly shorter	Reference	P = 0.03 (significant)
Treatment-Related SAEs	Zero	N/A	Favorable safety profile confirmed

Survival More Than Doubled

The headline finding: patients treated with JadiCell™ had a **Day-31 survival rate of 91%**, compared to just 42% in the control arm — a survival advantage of more than two-to-one. This result reached statistical significance at P = 0.015, meaning the likelihood of this result occurring by chance is less than 1.5%. For context, ARDS clinical trials have historically struggled to demonstrate even modest survival benefit; a result of this magnitude is considered scientifically notable.

Serious Adverse Events Cut by 87%

The safety profile reinforced the efficacy signal. Patients in the JadiCell™ group experienced only **2 serious adverse events**, compared to **16 in the placebo group** — an 87.5% reduction (P = 0.008). Critically, zero treatment-related serious adverse events were attributable to the JadiCell™ infusions themselves, establishing a compelling safety-tolerability foundation for the larger pivotal trial.

Faster Recovery

Time to recovery was significantly shorter in the JadiCell™ group (P = 0.03), suggesting that the therapy's proposed mechanism of immune modulation may translate into measurable clinical acceleration of the healing process — reducing the duration of mechanical ventilation, ICU stay, and hospital resource utilization.

The Cytokine Story

Perhaps most mechanistically compelling were the inflammatory biomarker data. Key cytokines — the molecular drivers of ARDS-related lung destruction — showed marked reductions in the JadiCell™ group. The published trial reported:

> *"Marked and statistically significant decreases" in key inflammatory cytokines including IL-6, TNF-*
>
> *α*
>
> *, IFN-*
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> *γ*
>
> *, PDGF-BB, and RANTES in JadiCell™-treated patients compared to controls.*
>
> — STEM CELLS Translational Medicine (2021)

These findings provide direct biological evidence that JadiCell™ is engaging the intended mechanism — actively modulating the cytokine cascade responsible for ARDS progression — and are not simply a statistical artifact.

⚠ Context & Appropriate Caveats — For Responsible Reporting

The Phase 1/2a trial enrolled 24 patients, and while results are statistically significant and peer-reviewed, findings from early-phase trials in small populations require confirmation in larger studies before regulatory conclusions can be drawn. Breathe Biologics is advancing a 128-patient Phase 2b/3 pivotal trial to provide the definitive evidence base. Journalists are encouraged to

characterize results as "promising early-phase clinical data" and to include the required regulatory disclaimer.

Publication Reference (For Citation in Press Coverage)

The Phase 1/2a trial results are published in: *STEM CELLS Translational Medicine*, 2021. The trial is registered at ClinicalTrials.gov. Breathe Biologics' communications team can provide the full citation and DOI upon media request.

Section 5 What's Next — Pipeline & Upcoming Milestones

Building on the Phase 1/2a foundation, Breathe Biologics is preparing to launch a pivotal Phase 2b/3 randomized controlled trial — the definitive step toward potential FDA review of JadiCell™ for the treatment of ARDS.

Clinical Pipeline

Trial Stage	Program	Status	Key Details
Phase 2b/3 Pivotal	JadiCell™ for ARDS	Not Yet Recruiting	128 patients; up to 6 U.S. investigational sites; NCT07479043; IND #19757
Future Indication (Exploratory)	Trauma / Sepsis-Induced ARDS	Exploratory — Pre-Clinical Stage	Based on Phase 1/2a mechanistic signals; sepsis is among the leading causes of ARDS
Future Indication (Exploratory)	Viral Respiratory Failure	Exploratory — Pre-Clinical Stage	Based on proposed JadiCell™ mechanism of cytokine storm modulation in viral lung injury

Upcoming Key Milestones

- **Trial Site Activation:** Investigational site qualification and activation across up to 6 U.S. clinical centers
- **First Patient Enrolled:** Initiation of the Phase 2b/3 randomized controlled trial
- **Interim Data Readout:** Pre-specified interim analysis to assess safety and preliminary efficacy
- **Full Data Readout:** Anticipated upon completion of 128-patient enrollment and follow-up
- **Regulatory Filing:** Preparation of NDA/BLA filing package contingent on pivotal trial outcome

Why This Matters for Patients

If the Phase 2b/3 trial confirms the Phase 1/2a findings, JadiCell™ could become the **first disease-modifying pharmacologic therapy ever approved for ARDS** — a medical milestone that would affect tens of thousands of patients annually and fundamentally change how critical care physicians treat the condition. For families facing an ARDS diagnosis, this trial represents a meaningful source of clinical hope.

Trial Registration

Registry	Number
ClinicalTrials.gov NCT Number	NCT07479043
FDA Investigational New Drug (IND) Application	IND #19757
U.S. Patent	9,803,176 B2

Section 6 Frequently Asked Questions — Media FAQ

The following Q&A pairs are intended to assist journalists and editors in accurately representing Breathe Biologics and JadiCell™ in published coverage. All answers are approved for paraphrase; direct quotes from company representatives are available upon request.

Q1: What is JadiCell™?

JadiCell™ is Breathe Biologics' patented investigational technology, derived from the subepithelial layer of umbilical cord tissue and protected under U.S. Patent No. 9,803,176 B2. It is administered intravenously and is designed to modulate the inflammatory cytokine cascade responsible for the lung destruction observed in ARDS. JadiCell™ is an off-the-shelf therapy, meaning it is manufactured in advance and does not require cell harvesting from individual patients.

Q2: Is JadiCell™ FDA-approved?

No. JadiCell™ is an investigational therapy and has not been approved by the FDA for any indication. The company is preparing to advance JadiCell™ into a pivotal Phase 2b/3 randomized controlled clinical trial (NCT07479043) under IND #19757. FDA approval would require successful completion of the pivotal trial, regulatory review, and agency authorization — a process that will take additional years.

Q3: What is ARDS and who does it affect?

Acute Respiratory Distress Syndrome (ARDS) is a life-threatening inflammatory condition of the lungs triggered by events including pneumonia, sepsis, trauma, and severe viral respiratory illness. In ARDS, the immune system's response becomes dysregulated, causing severe lung inflammation and fluid accumulation that prevents normal oxygen exchange. ARDS affects more than 190,000 Americans annually and carries a mortality rate of 30 to 45 percent — making it deadlier each year than breast cancer in terms of U.S. lives lost. Currently, no FDA-approved pharmacologic therapy exists that targets the root cause of ARDS.

Q4: What were the results of the Phase 1/2a trial?

The Phase 1/2a trial — a double-blind, randomized, placebo-controlled study of 24 ARDS patients published in *STEM CELLS Translational Medicine* (2021) — demonstrated that JadiCell™-treated patients had a Day-31 survival rate of 91%, compared to 42% in the control group (P = 0.015). Serious adverse

events were reduced from 16 in the control group to just 2 in the JadiCell™ group (P = 0.008). Time to recovery was also significantly shorter in the JadiCell™ arm (P = 0.03). Zero treatment-related serious adverse events were observed. Inflammatory cytokines including IL-6, TNF-α, and IFN-γ showed marked and statistically significant decreases in the treatment group.

Q5: When will the Phase 2b/3 trial begin?

The Phase 2b/3 pivotal trial (NCT07479043) is currently in the preparation phase, with a status of "Not Yet Recruiting" as of September 2026. The trial is designed to enroll 128 patients across up to 6 U.S. investigational sites under IND #19757. The company expects to provide updated timelines on site activation and first patient enrollment through official communications and ClinicalTrials.gov updates. Media may contact Breathe Biologics' communications team for the most current milestone guidance.

Q6: How is JadiCell™ different from other stem cell therapies?

Several features distinguish JadiCell™ from other cell therapy approaches. First, JadiCell™ is a patented technology derived from the subepithelial layer of umbilical cord tissue, a neonatal source with characteristics that support allogeneic use. Second, it is protected under U.S. Patent No. 9,803,176 B2 and is not a generic MSC preparation. Third, it is manufactured at scale under cGMP conditions, enabling an off-the-shelf deployment model that is clinically practical for ARDS — an acute condition where treatment delay can be fatal. Finally, JadiCell™ is the only UC-MSC therapy to have generated Phase 1/2a randomized controlled trial data in ARDS published in a peer-reviewed journal.

Q7: Is JadiCell™ related to COVID-19 treatment?

JadiCell™ is being developed primarily for ARDS broadly, not as a COVID-19-specific treatment. However, ARDS is a recognized complication of severe COVID-19 infection, and the proposed mechanism of JadiCell™ — modulation of the cytokine storm — is mechanistically relevant to viral respiratory failure of multiple etiologies, including COVID-19-induced ARDS. The company has listed viral respiratory failure as a future exploratory indication based on the mechanism. Journalists should note that the pivotal trial is focused on ARDS as a syndrome, not on any specific viral cause.

Q8: What is the source of the cells used in JadiCell™?

JadiCell™ is a patented technology derived from the subepithelial layer of donated human umbilical cord tissue. Following donation and rigorous testing, the mesenchymal stem cells are isolated, expanded, and manufactured under cGMP conditions. Because the cells come from a donor source rather than the individual patient, JadiCell™ is classified as an allogeneic therapy — enabling standardized batch manufacturing and off-the-shelf availability.

Q9: What is Breathe Biologics' commercial strategy?

Breathe Biologics' immediate commercial priority is the successful execution of the Phase 2b/3 pivotal trial and the generation of the clinical evidence base required for regulatory review. The company's longer-term commercial strategy — including potential partnerships, licensing arrangements, and commercialization pathways — will be communicated through official investor relations and corporate communications channels. Journalists seeking investor relations information should contact the communications team directly.

Q10: Where can I find the published research?

The Phase 1/2a trial results are published in *STEM CELLS Translational Medicine* (2021). The trial is also registered at ClinicalTrials.gov (NCT07479043). Breathe Biologics' media team can provide the full citation, DOI, and a media-use summary of the publication upon request. Journalists are encouraged to read the peer-reviewed paper directly and to consult independent ARDS clinical experts for third-party scientific perspective.

Section 7 Editorial Guidelines & Approved Language

Breathe Biologics is committed to supporting accurate, responsible journalism. The following guidelines are provided to assist editors and fact-checkers in ensuring published coverage meets both journalistic and regulatory standards.

Approved Company & Product Names

Name	Correct Usage	Notes
Company Name	Breathe Biologics, Inc.	Always include "Inc." on first reference. "Breathe Biologics" acceptable on subsequent references.
Product Name	JadiCell™	Always include the trademark symbol (™). "JadiCell" without the symbol is incorrect.
Condition Treated	Acute Respiratory Distress Syndrome (ARDS)	Spell out fully on first reference; ARDS acceptable thereafter.
Cell Type	Mesenchymal cells derived from the subepithelial layer of umbilical cord tissue	Spell out fully on first reference.

Required Regulatory Disclaimer

⚠ **Required in All Published Pieces**

"JadiCell™ is an investigational therapy and has not been approved by the FDA for any indication."

This disclaimer must appear in any published article, broadcast segment, or digital content that describes JadiCell™ and its potential medical benefits. It may be integrated naturally into body copy or presented as a note. Breathe Biologics requests that media partners confirm its inclusion prior to publication.

Language to Avoid — And Suggested Alternatives

Do Not Use	Use Instead	Why
"Cure" / "Cures ARDS"	**"May treat" / "Investigational therapy for ARDS"**	JadiCell™ has not been proven to cure ARDS; use accurately reflects investigational status
"Proven" / "Proven effective"	**"Showed promising early-phase results" / "Demonstrated significant benefit in a Phase 1/2a trial"**	Phase 1/2a data requires confirmation in pivotal trial; "proven" implies regulatory-level evidentiary standard
"Approved" / "FDA-approved"	**"Investigational" / "In clinical trials"**	JadiCell™ has not received FDA approval for any indication
"Will work" / "Will save lives"	**"If approved, could provide" / "Has potential to"**	Efficacy in pivotal trial has not yet been established
"Miracle" / "Breakthrough cure"	**"Significant clinical finding" / "Promising investigational therapy"**	Superlative language overstates Phase 1/2a findings

Clinical Data Citation Standards

- Always cite the trial NCT number (NCT07479043) when referencing the Phase 2b/3 pipeline
- Always reference the *STEM CELLS Translational Medicine* publication when citing Phase 1/2a results
- Include IND number (IND #19757) when discussing regulatory status of the pivotal trial
- State trial phase and enrollment size when presenting efficacy data (e.g., "in a 24-patient Phase 1/2a trial")
- Do not present Phase 1/2a results as definitive without acknowledging the small sample size and the need for pivotal trial confirmation

Embargo Policy

Breathe Biologics may, from time to time, provide embargoed clinical, regulatory, or corporate news to credentialed media in advance of public announcement. Embargoed materials are provided under explicit written embargo terms. Acceptance of embargoed materials constitutes agreement to those terms. Violations may result in removal from the media list. Embargo requests should be directed to the communications team.

Image & Asset Availability

High-resolution images, including company logos, product imagery, and approved executive photography, are available from the Breathe Biologics communications team upon request and subject to usage rights confirmation. All images must be used in accordance with provided usage guidelines and must not be cropped, altered, or used in misleading contexts.

Section 8 Company Boilerplate — For Press Release Use

The following boilerplate is approved for use at the end of press releases and official Breathe Biologics news announcements. It should be reproduced verbatim or adapted only with prior written approval from Breathe Biologics communications.

About Breathe Biologics, Inc.

Breathe Biologics, Inc. is a clinical-stage biopharmaceutical company dedicated to transforming the treatment of Acute Respiratory Distress Syndrome (ARDS) — one of medicine's most urgent unmet needs. With its tagline, *Transforming Hope Into Healing*, Breathe Biologics is committed to advancing science with urgency, rigor, and compassion for the patients and families affected by this devastating condition. The company is headquartered at 4093 Oceanside Blvd., Suite B, Oceanside, CA 92056 and has established collaborative relationships with leading academic medical institutions, philanthropic organizations, and labor health advocates to support its clinical mission.

About JadiCell™

JadiCell™ is Breathe Biologics' patented investigational technology, derived from the subepithelial layer of umbilical cord tissue and manufactured as an allogeneic mesenchymal cell therapy under current Good Manufacturing Practice (cGMP) standards. Protected under U.S. Patent No. 9,803,176 B2, JadiCell™ is designed to modulate the dysregulated immune response — including the cytokine cascade — underlying ARDS, with the goal of improving survival outcomes and reducing the burden of serious adverse events. JadiCell™ is an off-the-shelf therapy that does not require patient-specific cell harvesting, making it uniquely suited for deployment in acute critical care settings. The Phase 1/2a randomized, double-blind,

placebo-controlled clinical trial of JadiCell™ in 24 ARDS patients, demonstrated a Day-31 survival rate of 91% in the treatment group versus 42% in controls (P = 0.015) and was published in *STEM CELLS Translational Medicine* in 2021.

Clinical Pipeline & Regulatory Status

Breathe Biologics is preparing to initiate a Phase 2b/3 pivotal randomized controlled trial of JadiCell™ in ARDS (NCT07479043; IND #19757), designed to enroll 128 patients across up to 6 U.S. investigational sites. The company is also exploring future indications in trauma/sepsis-induced ARDS and viral respiratory failure based on the mechanistic profile and early clinical signals of JadiCell™. **JadiCell™ is an investigational therapy and has not been approved by the FDA for any indication.** For more information, visit **www.breathebiologics.com**.

Section 9 Press Contact Information

All media inquiries, interview requests, embargoed material requests, and image asset requests should be directed to Breathe Biologics' communications team using the contact information below. The communications team is available to facilitate executive interviews, arrange scientific background briefings with appropriate team members, and provide supporting materials for published coverage.

Breathe Biologics — Media Relations

Primary Media Contact: Ed Johnson, CEO

Title: Chief Executive Officer

Email: Info@BreatheBiologics.com

Phone: 1-407-217-327

Website: www.breathebiologics.com

ClinicalTrials.gov: NCT07479043

Corporate Address: 4093 Oceanside Blvd., Suite B, Oceanside, CA 92056

🎓 Scientific / Clinical Media Inquiries

For Inquiries Regarding Dr. James Veltmeyer, M.D.:

Response Time Commitment

Breathe Biologics' communications team is committed to responding to all credentialed media inquiries within **one business day**. For time-sensitive publication deadlines, please indicate your deadline clearly in your initial inquiry. For breaking news or fast-turnaround requests, please call the direct media line.