

SHAREHOLDER ALERT: The Law Offices of Timothy L. Miles Announces Lawsuit Filed Against Mesoblast Limited (MESO)

Class Action Lawsuit Has Been Filed Against Mesoblast Limited by Investor; Shareholders Urged to Contact the Law Offices of Timothy L. Miles

HENDERSONVILLE, TN, UNITED STATES, October 10, 2020 /EINPresswire.com/ -- HENDERSONVILLE, TN / October 9, 2020/ The Law Offices of Timothy L. Miles, who has been leading the fight to protect shareholder rights for over 19 years, announces that a class action lawsuit has been filed in the United



States District Court for the Southern District of New York on behalf of investors that purchased Mesoblast Limited (NASDAQ: MESO) securities between April 16, 2019 and October 1, 2020 (the "Class Period"). The Mesoblast class action lawsuit was commenced on October 8, 2020 in the



We fight everyday, as we have the last 20 yesrs, to protect shareholder rights, enhance shareholder protections, recover losses for defrauded investors, and seek reform through enhanced governance"

Timothy L. Miles

Southern District of New York and is captioned Kristal v. Mesoblast Limited, No. 20-cv-08430. Investors have until December 7, 2020 to apply to the Court to be appointed as lead plaintiff in the lawsuit. The lawsuit seeks to recover investor losses under the federal securities laws.

Mesoblast Accused of Misleading Shareholders

Mesoblast develops allogeneic cellular medicines using its proprietary mesenchymal lineage cell therapy platform. Its lead product candidate, RYONCIL (remestemcel-L), is an investigational therapy comprising mesenchymal stem

cells derived from bone marrow. In February 2018, the Company announced that remestemcel-L met its primary endpoint in a Phase 3 trial to treat children with steroid refractory acute graft versus host disease ("aGVHD").

In early 2020, Mesoblast completed its rolling submission of its Biologics License Application ("BLA") with the FDA to secure marketing authorization to commercialize remestemcel-L for children with steroid refractory aGVHD.

On August 11, 2020, the FDA released briefing materials for its Oncologic Drugs Advisory Committee ("ODAC") meeting to be held on August 13, 2020. Therein, the FDA stated that Mesoblast provided post hoc analyses of other studies "to further establish the appropriateness of 45% as the null Day-28 ORR" for its primary endpoint. The briefing materials stated that, due to design differences between these historical studies and Mesoblast's submitted study, "it is unclear that these study results are relevant to the proposed indication."

On this news, the Company's share price fell \$6.09, or approximately 35%, to close at \$11.33 per share on August 11, 2020.

On October 1, 2020, Mesoblast disclosed that it had received a



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Complete Response Letter ("CRL") from the FDA regarding its marketing application for remestemcel-L for treatment of SR-aGVHD in pediatric patients. According to the CRL, the FDA recommended that the Company "conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD." The CRL also "identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity."

On this news, the Company's share price fell \$6.56, or 35%, to close at \$12.03 per share on October 2, 2020.

The complaint, filed on October 8, 2020, alleges that throughout the Class Period defendants made materially false and/or misleading statements, as well as failed to disclose material

adverse facts about the Company's business, operations, and prospects. Specifically, defendants failed to disclose to investors: (1) that comparative analyses between Mesoblast's Phase 3 trial and three historical studies did not support the effectiveness of remestemcel-L for steroid refractory aGVHD due to design differences between the four studies; (2) that, as a result, the FDA was reasonably likely to require further clinical studies; (3) that, as a result, the commercialization of remestemcel-L in the U.S. was likely to be delayed; and (4) that, as a result of the foregoing, defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Mesoblast Shareholders Urged to Contact the Firm

If you purchased Mesoblast securities, have information, or have any questions concerning this announcement or your rights or interests with respect to these matters, please contact Timothy L. Miles, Esquire, at 615-587-7384, Toll-Free at 855-846-6529, or by email to tmiles@timmileslaw.com. If you inquire by email please include your mailing address, telephone number, and the number shares owned.

About Timothy L. Miles

Timothy L. Miles is a nationally recognized shareholder rights attorney raised in Nashville, Tennessee. Mr. Miles was recentely awarded the recognition of American's Most Honored <u>Lawyers 2020 - Top 1% by the American Registry.</u> Mr. Miles was also recently selected by Martindale-Hubbell® and ALM as a 2020 Top Ranked Lawyer and a 2020 Top Rated Litigator. Mr. Miles also maintains the AV Preeminent Rating by Martindale-Hubbell[®], their highest rating for both legal ability and ethics. Mr. Miles is a member of the prestigious Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers Association, a superb rated attorney by Avvo, a recipient of the Lifetime Achievement Award by Premier Lawyers of America (2019) and recognized as a Distinguished Lawyer, Recognizing Excellence in Securities Law, by Lawyers of Distinction (2019-2020). Awards: Top Rated Litigator by Martindale-Hubbell® and ALM (2019); Elite Lawyer of The South by Martindale-Hubbell® and ALM (2019); Member of the Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers Association (2017-2019); AV® Preeminent™ Rating by Martindale-Hubble® (2014-2020); PRR AV Preeminent Rating on Lawyers.com (2018-2020); The Top-Rated Lawyer in Litigation™ for Ethical Standards and Legal Ability (Martindale-Hubble® 2015); Lifetime Achievement Award by Premier Lawyers of America (2019); Superb Rated Attorney (Avvo); Avvo Top Rated Lawyer for (Avvo 2017-2020). Mr. Miles has authored numerous publications advocating for shareholdings including most recently: Free Portfolio Monitoring Services Offered by Plaintiff Securities Firms Provides Significant Benefits To Investors (Timothy L. Miles, Dec. 3, 2019).

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SOURCE: The Law Offices of Timothy L. Miles

Leading the Fight to Protect Shareholder Rights for Over 19 Years

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