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Market Data as at May 29, 2015 ASX Code: .....BLT OTC Code ......BTEBY Market Cap: .....A\$ \$92,705,410 52 Week High/low: ......A\$1.37/0.52

# Shares on Issue: ......115,881,763

BENITEC ADVANCES

# BENITEC'S PROGRESS IN SILENCE

silenceworks

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**HEPATITIS C CLINICAL TRIAL** & SETS AGGRESSIVE **TARGETS FOR ALL PROGRAMS** (See below)

Hepatitis C	•				
	Efficacy Data	Complete Phase I/II			
Hepatitis B		•		0	
		Complete in vivo Proof of Concept	File IND	Initiate Phase I/II	
	•				
	Complete AAV Vector Development	Complete in vivo Proof of Concept		File IND	Initiate Phase I/
Drug-Resistant Non-Small Cell Lung Cancer	•				
		File IND			
OPMD		•			
		Complete Pre-Clinics Proof of Concept	al		

### Benitec sets 'aggressive but achievable' program targets In May, Benitec released our latest corporate presentation, in which we

outlined the milestones we expect to achieve with each of our pipeline programs, set following engagement with internal and external experts. Benitec regards the timely achievement of each of these targets as a measure of our success in progressing the company's ddRNAi programs towards clinical proof of concept and, ultimately, commercialisation. We plan to report our progress against these milestones regularly, in accordance with our ASX obligations. Benitec believes that we have set aggressive but achievable targets for each of the programs. See slide 32 for details.



## In March and April, we dosed patient four and five in our clinical trial of

TT-034 clinical trial progresses on several fronts

TT-034, completing the second cohort. All patients in the second cohort received the same dose of TT-034 (1.25 x 10^11 vg/kg), which is half a log higher than the dose administered to subjects in the first cohort. In April, Benitec initiated enrollment at a third US-based trial site at the Texas Liver Institute in San Antonio.



Benitec advances manufacturing capacity

In May, Benitec announced an agreement with Omnia Biologics to manufacture clinical product for the current clinical trial of TT-034 for hepatitis C. Production of the additional material ensures our ability to complete the trial, and may enable recruitment of additional patients, should they be required. Omnia Biologics has a well-established process for the manufacture of Adeno-Associated Virus (AAV)-based products that is comparable to the one currently used to produce the material for the TT-034 trial. In anticipation of requirements to serve the larger hepatitis B and C markets, Benitec is seeking to develop its own large scale manufacturing process for AAV-based products, in collaboration with third parties. **Details.** 



## CSIRO patent upheld in Europe and new patent granted in the US

In March, Benitec announced that the European Opposition division had upheld CSIRO's platform RNAi patent from the Waterhouse family (EP 1068311). Benitec is the exclusive worldwide licensee of this patent for human therapeutic application. In May, Benitec announced that the US Patent Office had granted US Patent 8,993,530 "RNAi expression constructs" covering constructs of multiple shRNA sequences targeting hepatitis C, the third in this family of patents. Also in May, the European Patent Office allowed the corresponding patent EP 09015950, which is expected to be granted soon. CSIRO remains a Benitec shareholder.



## Maxim says 'next paradigm shift...' and recommends BUY

In his March update, analyst Jason Kolbert from Maxim Group Equity Research compared the approaches to RNAi-based treatments taken by Benitec and other RNAi companies. Mr Kolbert referred to the single dose cure potential of Benitec's ddRNAi thus: 'The promise of such a cure could lead to the next paradigm shift in the space beyond direct-acting antivirals (DAAV)' and also said 'We assume that the clinical development of any single product to proof-of-concept studies will trigger a valuation increase.' Maxim set a 12 month price target for BLT at A\$4.00 and recommended BUY. Details.



## **Lodge Partners notes 'significant positive signal' maintains BUY** Commenting on Benitec's TT-034 clinical trial update on April 8, Lodge

Partners called it a 'major achievement' for Benitec. Lodge commented further that the announcement 'bodes very well for the company, the prospects of TT-034 and their general ddRNAi technology', maintaining a BUY recommendation and raising the 12 month price target to AS4.20 from A\$3.20. <u>Details.</u>



# On May 27, Benitec's licensee, Calimmune, announced completion of a

Benitec's ddRNAi licensee Calimmune raises \$15M

US\$15 million series B capital raise, led by a large pharmaceutical company and joined by existing investors including RA Capital and Translational Accelerator. The funds will be used to progress Calimmune's ongoing clinical trial of Cal-1, its gene-based therapy for treating HIV/AIDS. The successful raise highlights the growing support by investors and big pharmaceutical companies for treatments based on ddRNAi. Details.



ROTH Capital Partners

## Annual Roth Conference held on March 8-11 in Laguna Beach, California. Roth is a US-based investment bank with a strong track record of

Benitec's CSO presents to Roth Conference

investment in biotechnology and healthcare companies. This invitationonly conference attracted over 3,000 institutional investors, private equity investors, VCs, company executives and service providers from over 500 companies. Dr Suhy provided an overview of the company's ddRNAi technology, its mode of action, delivery mechanism, success in liver cell transduction and durability after just one injection. Details Benitec's CBO presents to Harvard Investors &ASX Spotlight

During March, Benitec's Chief Business Officer, Mr Carl Stubbings addressed two different groups: the Harvard Investors lunch of over 100 retail, private

Benitec's Chief Scientific Officer, Dr David Suhy, presented to the 27th



### and institutional investors held in New York on March 4, and the ASX Spotlight Conference also held in New York on March 5th. Carl presented an update

of the company's clinical trial of TT-034 for hepatitis C and progress of the company's other pipeline programs, including drug-resistant lung cancer and age-related macular degeneration. <u>Benitec&collaborators present to AGCTS conference in Melbourne</u> Benitec and our associated collaborators filled several key speaking



# the clinical trial for ddRNAi-based TT-034 for hepatitis C, and Prof Maria

slots at the 9th Biennial Conference of the Australasian Gene and Cell Therapy Society, held in Melbourne on April 29, 2015. Dr Suhy, Benitec's Chief Scientific Officer, presented a previously un-released update of

Kavallaris, Benitec's collaborator from University of New South Wales, presented an update of the development of ddRNAi-based Tribetarna to treat chemotherapy-resistant lung cancer. Benitec's CEO and MD, Dr Peter French, presented an overview of Benitec's ddRNAi portfolio. Prof David Schaffer, Chief Scientific Officer at US-based 4D Molecular Therapeutics, which is developing a novel retinal delivery vector for Benitec, gave an overview of the scientific approach using directed evolution to produce AAV vectors with specific tropism and low immunogenicity.



Staff additions, changes and moves Benitec's former Chief Scientist, Dr Michael Graham, has relocated from Australia to the USA, joining the scientific team at Benitec's Bremner Laboratory in San Francisco as Founding Scientist and Head of Discovery, where he'll focus on developing new technologies. Dr David Suhy, head of the Bremner Laboratory, has been appointed as Chief Scientific Officer, with Dr Peter Roelvink, Senior Director of Research, working as his deputy. Peter has a long track record working with ddRNAi, and was an inventor on several Benitec patents. Ms Georgina Kilfoil has been appointed Chief Clinical Officer and has relocated from the United States to Sydney. We have appointed a VP of Manufacturing, Dr Claudia Kloth, who has had significant



expertise in manufacturing gene therapy vectors. Dr Kloth is based in New Jersey. Ms Sakura Holloway has added SVP Corporate Development to her title of IP Counsel to indicate an expanded role in the senior management of

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the Company's IP-related activities.