Intec Pharma Reports First Quarter 2019 Financial Results and Corporate Update

May 7, 2019

JERUSALEM, May 7, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the three months ended March 31, 2019 and provides a corporate update.

Highlights of the first quarter 2019 and recent weeks include:

- Announced that the last patient completed their final visit in the Company's pivotal Phase 3 trial (the ACCORDANCE trial) evaluating the safety and efficacy of the Accordion Pill®-Carbidopa/Levodopa (AP-CD/LD) compared with immediate release CD/LD (IR-CD/LD; Sinemet®) as a treatment for the symptoms of advanced Parkinson's disease (PD);
- Reported positive data from a pharmacokinetic (PK) study of AP-CD/LD 50/500 mg in PD patients, demonstrating that AP-CD/LD when dosed three times per day (TID) met the primary endpoint of reducing plasma levodopa variability when compared to standard oral CD/LD dosed five times per day (p=0.0048);
- Announced that data from the PK study of AP-CD/LD 50/500 mg TID were accepted for poster presentation at the XXIV World Congress on Parkinson's Disease and Related Disorders taking place June 16 -19, 2019 in Montreal, Canada;
- Completed the analysis of a PK study of AP-tetrahydrocannabinol (THC), showing AP-THC to be generally safe and well tolerated, but finding this particular AP structure, which was specifically designed for this study, did not fully meet the Company's internal expectations; and
- Initiated the PK study of the Accordion Pill developed for a proprietary compound under the previously announced feasibility and option agreement with Novartis Pharmaceuticals.

Management Commentary

"Since the beginning of 2019, we continued to execute on our strategic initiatives to build our Accordion Pill platform technology and advance our clinical development programs. We are especially pleased with the progress we made with the AP-CD/LD development program, which keeps us on track to report topline results from this pivotal Phase 3 trial in advanced Parkinson's patients this summer," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"During the first quarter, we announced positive data from the AP-CD/LD 50/500 mg TID PK study. These results were especially encouraging as they demonstrated a statistically significant reduction in plasma LD variability, which many Parkinson's disease experts believe is a proxy for efficacy. These PK data using the most common dose in our Phase 3 ACCORDANCE study are encouraging and support our confidence in this pivotal program. We look forward to having these favorable data presented at the World Congress on Parkinson's Disease and Related Disorders next month.

"We continue to make progress with our pre-commercial activities for AP-CD/LD, with a view to enhancing partnership opportunities for this late-stage asset. Our ongoing payor research confirms the need for better baseline LD treatment and concluded that peak U.S. base case annual gross revenues in excess of $300 million are possible with appropriate pricing and access. Together with our partner, LTS LohmanTherapie-Systeme, we made meaningful progress this last quarter with our commercial scale manufacturing processes. In the coming months, we intend to begin the validation, bioequivalency and stability studies that are designed to position us to file for regulatory submission and to support a commercial launch. As a result, we remain confident we are on track to submit a New Drug Application for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data.

"During the quarter, we were very excited to initiate the human PK study of our AP for a Novartis propriety compound. Previously, our Intec team successfully created a customized AP for Novartis' proprietary compound that met the required *invitro* specifications set forth in our feasibility agreement. We hope to take the next step in our relationship with Novartis with this *in vivo* study. This partnership holds significant promise as the market opportunity for this proprietary compound is in excess of $1 billion.

"Regarding our cannabis development program, we were disappointed that the initial custom designed AP delivery system in the AP-THC PK study didn't meet our expectations. Our ongoing development work provides a deeper understanding of how to best apply gastric retention technology to enhance the delivery of this poorly soluble class of molecules. Development of new AP designs is an iterative process, and just as we did for the design of our AP-CD/LD, we will continue to optimize the cannabinoid AP to fully meet our specifications for the oral delivery of THC and CBD. Moving forward, new designs of the AP will likely be required to advance the cannabis program and we expect to provide new timelines for the cannabinoid AP clinical development program before the end of the year.

"With topline data readout expected in the coming months, we are closer than ever to achieving our vision to bring a better baseline levodopa treatment to Parkinson's patients suffering with the motor complications of this degenerative disease. Before the end of 2019, we have two significant opportunities to monetize our Accordion Pill platform assets: our PD program and our Novartis partnership. Moving forward, we expect to build our Accordion Pill drug delivery platform with the addition of both partner-sponsored R&D programs, such as Novartis, and through internally-led drug reformulation programs, such as our PD program. We believe this strategy provides the best opportunities for both short- and long-term growth," concluded Mr. Meckler.

First Quarter 2019 Financial Results

Research and development expenses, net, for the three-month period ended March 31, 2019 were approximately $8.5 million, a decrease of approximately $400,000, or 4%, compared with approximately $8.9 million for the first quarter of 2018. The decrease was primarily due to a decrease in expenses related to our ACCORDANCE study and open label extension study, offset by an increase in expenses related to the scale up activities for the commercial-scale production capabilities for AP-CD/LD at LTS.

General and administrative expenses for the three-month period ended March 31, 2019 were approximately $2.2 million, an increase of approximately $300,000, or 16%, compared with approximately $1.9 million in the three-month period ended March 31, 2018. The increase was primarily related to the increase in payroll and related expenses mainly due to an increase in headcount and salary raises and insurance expenses, offset by a decrease in professional services.

Net loss for the three-month period ended March 31, 2019 and 2018 was approximately $10.7 million.

Loss per ordinary share for the three-month period ended March 31, 2019 was $0.32 compared with a loss per ordinary share of $0.41 for the three-month period ended March 31, 2018.

As of March 31, 2019, the Company had cash and cash equivalents and marketable securities of approximately $32.3 million compared with approximately $40.6 million at December 31, 2018.

Net cash used in operating activities during the three-month period ended March 31, 2019 was approximately $7.3 million compared with net cash used in operating activities of approximately $10.3 million during the three-month period ended March 31, 2018. This decrease resulted primarily from changes in operating asset and liability items of approximately $2.6 million and a decrease in expenses paid in cash in the current quarter compared to the three months ended March 31, 2018.

The Company had negative cash flow from investing activities of approximately $640,000 during the three-month period ended March 31, 2019 compared to negative cash flow from investing activities of approximately $2.0 million during the three-month period ended March 31, 2018. This decrease resulted primarily from a decrease in purchase of property and equipment in the amount of approximately $2.0 million and proceeds from the disposal of marketable securities in the amount of approximately $500,000. This was offset by an approximate $1.2 million investment in other assets related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS.

Net cash provided by financing activities during the three-month period ended March 31, 2019 was approximately $161,000, which was provided by the proceeds from the exercise of options by employees. During the three-month period ended March 31, 2018, the Company had no financing activities.

About Intec Pharma Ltd.

Intec Pharma is a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology. The Company's Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention and specific release mechanism. The Company's product pipeline includes two product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, which is in late-stage Phase 3 development for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for various pain indications. In addition, the Company has a feasibility agreement for the development of a custom-designed Accordion Pill for a proprietary compound with Novartis Pharmaceuticals.

For more information, visit www.intecpharma.com. Intec Pharma routinely posts information that may be important to investors in the Investor Relations section of its website.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward looking statements about our expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our limited operating history and history of operating losses, our ability to continue as a going concern, our ability to obtain additional financing, our ability to successfully operate our business or execute our business plan, the timing and cost of our clinical trials, the completion and receiving favorable results in our clinical trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to protect and maintain our intellectual property and licensing arrangements, our ability to develop, manufacture and commercialize our product candidates, the risk of product liability claims, the availability of reimbursement, and the influence of extensive and costly government regulation. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in our most recent Annual Report on Form 10-K filed with the SEC on February 27, 2019, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

-Tables to Follow-

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31 2019	December 31 2018
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 31,497	$ 39,246
Investment in marketable securities	757	1,333
Prepaid expenses and other receivables	2,685	2,986
TOTAL CURRENT ASSETS	34,939	43,565
NON-CURRENT ASSETS:		
Other assets	6,792	5,431
Property and equipment, net	12,487	12,233
Operating lease right-of-use assets	2,047	-
Deferred tax assets	350	281
TOTAL NON-CURRENT ASSETS	21,676	17,945
TOTAL ASSETS	$ 56,615	$ 61,510
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 3,487	$ 2,849
Other	7,245	4,807
TOTAL CURRENT LIABILITIES	10,732	7,656
LONG-TERM LIABILITIES -		
Non-current operating lease liabilities	1,409	-
Other liabilities	385	309
TOTAL LONG-TERM LIABILITIES	1,794	309
TOTAL LIABILITIES	12,526	7,965
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 Ordinary Shares as of March 31, 2019 and December 31, 2018; issued and outstanding: 33,297,371 and 33,232,988 Ordinary Shares as of March 31, 2019 and December 31, 2018, respectively	727	727
Additional paid-in capital	195,842	194,642
Accumulated deficit	(152,480)	(141,824)
TOTAL SHAREHOLDERS' EQUITY	44,089	53,545
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 56,615	$ 61,510

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31	
	2019	2018
	U.S. dollars in thousands	
OPERATING EXPENSES:		
RESEARCH AND DEVELOPMENT EXPENSES, net	$ (8,542)	$ (8,880)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,190)	(1,910)
OPERATING LOSS	(10,732)	(10,790)
FINANCIAL INCOME, net	110	124
LOSS BEFORE INCOME TAX	(10,622)	(10,666)
INCOME TAX	(34)	(63)
NET LOSS	$ (10,656)	$ (10,729)
	$	
LOSS PER SHARE BASIC AND DILUTED	$ (0.32)	$ (0.41)

WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	33,247	26,076

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CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(Unaudited)

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of shares	Amounts	Amounts		
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2018	26,075,770	$ 727	$ 156,356	$ (98,281)	$ 58,802
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2018:					
Share-based compensation	-	-	723	-	723
Net loss	-	-	-	(10,729)	(10,729)
BALANCE AT MARCH 31, 2018	26,075,770	$ 727	$ 157,079	$ (109,010)	$ 48,796
BALANCE AT JANUARY 1, 2019	33,232,988	$ 727	$ 194,642	(141,824)	$ 53,545
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2019:					
Exercise of options	64,383	-	257	-	257
Share-based compensation	-	-	943	-	943
Net loss	-	-	-	(10,656)	(10,656)
BALANCE AT MARCH 31, 2019	33,297,371	$ 727	$ 195,842	$ (152,480)	$ 44,089

INTEC PHARMA LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31	
	2019	2018
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (10,656)	$ (10,729)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	218	206
Exchange differences on cash and cash equivalents	8	(40)
Right of use asset	163	
Lease liability	(98)	-
Losses on marketable securities	-	73
Share-based compensation	943	723
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other receivables	340	(98)
Increase in deferred tax assets	(69)	-
Increase (decrease) in accounts payable and accruals	1,813	(390)
Increase in other liabilities	76	-
Net cash used in operating activities	(7,262)	(10,255)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(10)	(2,022)
Investment in other assets	(1,206)	-
Proceeds from disposal of marketable securities, net	576	46
Net cash used in investing activities	(640)	(1,976)
CASH FLOWS FROM FINANCING ACTIVITIES:		

Proceeds from exercise of options	161	-
Net cash provided by financing activities	161	-
DECREASE IN CASH AND CASH EQUIVALENTS	(7,741)	(12,231)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	39,246	53,393
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(8)	40
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 31,497	$ 41,202
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Liability with respect to property and equipment	$ 462	$ -
Liability with respect to other assets	648	$ -
Receivables with respect to exercise of options	$ 96	$ -
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:		
Interest received	$ 128	$ 117

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